**PRODUCT DESCRIPTION**

**Salbutamol + Guaifenesin (Ventolin® Expectorant) Capsule:** Grey and blue, hard gelatin capsules marked with 'VENTOLIN EXpectorant' and 'GlaxoSmithKline'. Each capsule contains 100mg Guaifenesin and 2mg Salbutamol (as sulfate).

**Salbutamol + Guaifenesin (Ventolin® Expectorant) Syrup Sugar Free:** Each 5mL of orange flavored syrup contains 50mg Guaifenesin and 1.0mg Salbutamol (as sulfate).

**PHARMACOLOGICAL PROPERTIES**

**Mechanism of action**
Salbutamol is a selective beta-2 adrenoceptor agonist. At therapeutic doses it acts on the beta-2 adrenoceptors of bronchial muscle.
Guaifenesin can make the viscous mucus of the respiratory pathway more fluid and therefore expectoration and reduces cough.

**Pharmacodynamic Effects**
Salbutamol is a selective beta2-adrenoceptor agonist. At therapeutic doses it acts on the beta2-adrenoceptors of bronchial muscle providing short acting (4 to 6 hour) bronchodilation in reversible airways obstruction.

**Pharmacokinetics**

**Absorption**
After oral administration, salbutamol is absorbed from the gastrointestinal tract and undergoes considerable first-pass metabolism to the phenolic sulfate. Both unchanged drug and conjugate are excreted primarily in the urine.
Guaifenesin is well-absorbed after oral administration. After the administration of 600 mg guaiphenesin in healthy adult volunteers the Cmax was approx 1.4 micrograms/ml with Tmax about 15 minutes after drug administration.

**Distribution**
The bioavailability of orally administered salbutamol is about 50%. Salbutamol is bound to plasma proteins to the extent of 10%.

**Metabolism**
Salbutamol administered intravenously has a half-life of 4 to 6 hours and is cleared partly renally and partly by metabolism to the inactive 4’-O-sulfate (phenolic sulfate) which is also excreted primarily in the urine.
Guaiphenesin has a plasma half-life of approx 1 hour and was not detectable in the blood after 8 hours. Guaiphenesin appears to undergo both oxidation and demethylation.

**Elimination**
The majority of a dose of salbutamol given intravenously, orally or by inhalation is excreted within 72 hours. The faeces are a minor route of excretion.
Guaiphenesin is excreted in urine.

**Non-clinical Information**
In common with other potent selective beta-2 receptor agonists, salbutamol has been shown to be teratogenic in mice when given subcutaneously. In a reproductive study, 9.3% of foetuses were found to have cleft palate, at 2.5mg/kg, 4 times the maximum human oral dose. In rats, treatment at the levels of 0.5, 2.32, 10.75 and 50mg/kg/day orally throughout pregnancy resulted in no significant foetal abnormalities. The only toxic effect was an increase in neonatal mortality at the highest dose level as the result of lack of maternal care. A reproductive study in rabbits revealed cranial malformations in 37% of foetuses at 50mg/kg/day, 78 times the maximum human oral dose.
Reproduction studies in rats demonstrated no evidence of impaired fertility at oral doses of salbutamol up to 50 mg/kg.
Animal studies on guaiphenesin to assess carcinogenicity, genotoxicity, or effects on fertility or embryo-fetal development have not been performed.

**INDICATIONS**
Salbutamol is a selective beta-2 adrenoceptor agonist indicated for the treatment or prevention of bronchospasm. It provides short acting (four hours) bronchodilation in reversible airways obstruction due to asthma, chronic bronchitis and emphysema.
Bronchodilators should not be the only or main treatment in patients with persistent asthma. In patients with persistent asthma unresponsive to salbutamol, treatment with inhaled corticosteroids is recommended to achieve and maintain control. Failing to respond to treatment with salbutamol may signal a need for urgent medical advice or treatment.
The combination of salbutamol with guaifenesin is designed to relieve respiratory obstruction and improve pulmonary ventilation.
Respiratory disorders where bronchospasm and excessive secretion of tenacious mucus are complicating factors, e.g. bronchial asthma, chronic bronchitis and emphysema.

**DOSAGE AND ADMINISTRATION**
Salbutamol has a duration of action of 4 to 6 hours in most patients.
Increasing use of beta-2 agonists may be a sign of worsening asthma. Under these conditions a reassessment of the patient’s therapy plan may be required and concomitant glucocorticosteroid therapy should be considered.
As there may be adverse effects associated with excessive dosing, the dosage or frequency of administration should only be increased on medical advice.
Effects on Ability to Drive and Use Machines

It is important that adequate dental hygiene is maintained. Long term treatment with salbutamol and guaiphenesin expectorant syrup (sugar-containing formulation) increases the risk of increased blood sugar levels. The diabetic patient may be unable to compensate for this and the development of ketoacidosis has been reported. Concurrent administration of corticosteroids can exaggerate this effect. Potentially serious hypokalaemia may result from beta-2 agonist therapy mainly from parenteral and nebulised administration. Salbutamol should be administered cautiously to patients with thyrotoxicosis. Patients should be warned that if either the usual relief is diminished or the usual duration of action reduced, they should not increase the dose or its frequency of administration, but should seek medical advice.

ADVERSE EFFECTS

As the combination product contains salbutamol and guaiphenesin, the type and severity of adverse reactions associated with each of the components may be expected. The adverse reaction profile is derived from the individual components since there are limited clinical and post marketing reports available for the combination product. Adverse reactions are listed below by system organ class and frequency. Frequencies are defined as: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1000 to <1/100), rare (≥1/10,000 to <1/1000) and very rare (<1/10,000) including
isolated reports. Very common and common reactions were generally determined from clinical trial data. Rare and very rare reactions were generally determined from spontaneous data.

Salbutamol

**Immune system disorders**
- Very rare: Hypersensitivity reactions including angioedema, urticaria, bronchospasm, hypotension and collapse.

**Metabolism and nutrition disorders**
- Rare: Hypokalaemia.

**Potentially serious hypokalaemia may result from beta-2 agonist therapy.**

**Nervous system disorders**
- Very common: Tremor.
- Common: Headache.
- Very rare: Hyperactivity.
- Common: Tachycardia, palpitations.
- Rare: Cardiac arrhythmias including atrial fibrillation, supraventricular tachycardia and extrasystoles.

**Vascular disorders:**
- Rare: Peripheral vasodilatation.

**Musculoskeletal and connective tissue disorders**
- Common: Muscle cramps.
- Rare: Feeling of muscle tension.

**Cardiac disorders**
- Common: Tachycardia, palpitations.
- Rare: Cardiac arrhythmias including atrial fibrillation, supraventricular tachycardia and extrasystoles.

**Guaiphenesin**

**Immune system disorders**
- Unknown: Hypersensitivity and allergic reactions including anaphylactic reactions, angioedema, rash, urticaria and dyspnoea.

**Gastrointestinal disorders**
- Unknown: Nausea, vomiting, abdominal discomfort.

**OVERDOSAGE AND TREATMENT**

**Overdosage**
The most common signs and symptoms of overdose with salbutamol are transient beta agonist pharmacologically mediated events (see Warnings and Precautions and Adverse Reactions).

Hypokalaemia may occur following overdose with salbutamol. Serum potassium levels should be monitored.

Lactic acidosis has been reported in association with high therapeutic doses as well as overdoses of short-acting beta-agonist therapy, therefore monitoring for elevated serum lactate and consequent metabolic acidosis (particularly if there is persistence or worsening of tachypnea despite resolution of other signs of bronchospasm such as wheezing) may be indicated in the setting of overdose.

**Very large doses of guaiphenesin cause nausea and vomiting.**

**Treatment**
Further management should be as clinically indicated or as recommended by the national poisons centre, where available.

**INCOMPATIBILITY**
Salbutamol + Guaifenesin (Ventolin® Expectorant) syrup: Dilution with Syrup BP or Sobitol solution is not recommended as this may result in precipitation of the cellulose thickening agent. Admixture of Salbutamol + Guaifenesin (Ventolin® Expectorant) Syrup with other liquid preparations is not recommended.

**Excipients**
- Hydroxypropyl methylcellulose
- Sodium benzoate
- Saccharin sodium
- Lactic acid
- Orange flavour (IFF 17.40.0095)
- Mint Essence
- Silica
- Maize starch
- Purified water

**STORAGE CONDITION**
Salbutamol + Guaifenesin (Ventolin® Expectorant) Capsule: Store at temperatures not exceeding 30°C.

Salbutamol + Guaifenesin (Ventolin® Expectorant) Syrup: Stored at a temperatures not exceeding 30°C. Protect from light.

**INSTRUCTION FOR USE/HANDLING**
Dilution:
Sugar-free formulation:
Salbutamol and guaiphenesin expectorant syrup may be diluted with Purified Water BP. The resulting mixture should be protected from light and used within 28 days.

A 50% v/v dilution of salbutamol and guaiphenesin expectorant syrup has been shown to be adequately preserved against microbial contamination. However, to avoid the possibility of introducing excessive microbial contamination, the Purified Water BP used for dilution should be recently prepared or alternatively it should be boiled and cooled immediately before use.
AVAILABILITY
Ventolin® Expectorant Capsule: Strip foil by 10’s (Box of 50’s)
Ventolin® Expectorant Syrup Sugar Free: Bottles of 60 and 120mL.

CAUTION
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.
Keep all medicines out of reach of children.

VENTOLIN is a registered trademark of the GlaxoSmithKline group of companies.
© 2014, GlaxoSmithKline group of companies. All rights reserved.

Version number: GDS16 Revision date: 05 February 2014
Salbutamol sulphate
Ventolin®
2mg Tablet

PRODUCT DESCRIPTION
Each white, circular, flat faced tablet with bevelled edges, engraved on one face with “GX/CN3” contains 2mg salbutamol, as sulphate.

PHARMACOLOGICAL PROPERTIES
Pharmacodynamics
Salbutamol is a selective beta-2 adrenoceptor agonist. At therapeutic doses it acts on the beta-2 adrenoceptors of bronchial muscle providing short acting (4 to 6 hour) bronchodilation in reversible airways obstruction.

Pharmacokinetics
Salbutamol administered intravenously has a half-life of 4 to 6 hours and is cleared partly renally and partly by metabolism to the inactive 4'-O-sulphate (phenolic sulphate) which is also excreted primarily in the urine. The faeces are a minor route of excretion. Salbutamol is bound to plasma proteins to the extent of 10%.

After oral administration, salbutamol is absorbed from the gastrointestinal tract and undergoes considerable first-pass metabolism to the phenolic sulphate. Both unchanged drug and conjugate are excreted primarily in the urine. The bioavailability of orally administered salbutamol is about 50%.

Pre-clinical Safety Data
In common with other potent selective beta-2 receptor agonists, salbutamol has been shown to be teratogenic in mice when given subcutaneously. In a reproductive study, 9.3% of foetuses were found to have cleft palate, at 2.5mg/kg, 4 times the maximum human oral dose. In rats, treatment at the levels of 0.5, 2.32, 10.75 and 50mg/kg/day orally throughout pregnancy resulted in no significant foetal abnormalities. The only toxic effect was an increase in neonatal mortality at the highest dose level as the result of lack of maternal care. A reproductive study in rabbits revealed cranial malformations in 37% of foetuses at 50mg/kg/day, 78 times the maximum human oral dose.

INDICATIONS
Salbutamol (Ventolin®) is a selective beta-2 adrenoceptor agonist indicated for the treatment or prevention of bronchospasm. It provides short acting bronchodilation in reversible airways obstruction due to asthma, chronic bronchitis and emphysema.

Bronchodilators should not be the only or main treatment in patients with persistent asthma. In patients with persistent asthma unresponsive to Salbutamol (Ventolin®), treatment with inhaled corticosteroids is recommended to achieve and maintain control. Failing to respond to treatment with Salbutamol (Ventolin®) may signal a need for urgent medical advice or treatment.

Salbutamol (Ventolin®) tablets are indicated for the relief of bronchospasm in bronchial asthma of all types, chronic bronchitis and emphysema.

DOSAGE AND ADMINISTRATION
Salbutamol (Ventolin®) has a duration of action of 4 to 6 hours in most patients.

Increasing use of beta-2 agonists may be a sign of worsening asthma. Under these conditions a reassessment of the patient’s therapy plan may be required and concomitant glucocorticosteroid therapy should be considered.

As there may be adverse effects associated with excessive dosing, the dosage or frequency of administration should only be increased on medical advice.

• Adults
The usual effective dose is 4 mg (2 tablets) 3 or 4 times per day.
If adequate bronchodilation is not obtained each single dose may be gradually increased to as much as 8 mg (4 tablets). Some patients obtain adequate relief with 2 mg (1 tablet) 3 or 4 times daily.

• Children
2 - 12 years 2 mg (1 tablet) 3 or 4 times daily.
Over 12 year 2 to 4 mg (1 to 2 tablets) 3 or 4 times daily.

• Special patient groups
In elderly patients or in those known to be unusually sensitive to beta-adrenergic stimulant drugs, it is advisable to initiate treatment with 2 mg (1 tablet) salbutamol 3 or 4 times per day.

CONTRAINdications
Salbutamol (Ventolin®) Tablets are contra-indicated in patients with a history of hypersensitivity to any of their components.

Non-i.v. formulations of VENTOLIN must not be used to arrest uncomplicated premature labour or threatened abortion.
WARNINGS AND PRECAUTIONS
The management of asthma should normally follow a stepwise programme, and patient response should be monitored clinically and by lung function tests. Increasing use of short-acting inhaled beta-2 agonists to control symptoms indicates deterioration of asthma control. Under these conditions, the patient’s therapy plan should be reassessed. Sudden and progressive deterioration in asthma control is potentially life-threatening and consideration should be given to starting or increasing corticosteroid therapy. In patients considered at risk, daily peak flow monitoring may be instituted.

Patients should be warned that if either the usual relief is diminished or the usual duration of action reduced, they should not increase the dose or its frequency of administration, but should seek medical advice.

Salbutamol (Ventolin®) should be administered cautiously to patients with thyrotoxicosis. Potentially serious hypokalaemia may result from beta-2 agonist therapy mainly from parenteral and nebulised administration. Particular caution is advised in acute severe asthma as this effect may be potentiated by concomitant treatment with xanthine derivatives, steroids, diuretics and by hypoxia. It is recommended that serum potassium levels are monitored in such situations.

In common with other beta-adrenoceptor agonists, Salbutamol (Ventolin®) can induce reversible metabolic changes, for example increased blood sugar levels. The diabetic patient may be unable to compensate for this and the development of ketacidosis has been reported. Concurrent administration of corticosteroids can exaggerate this effect.

Effects on Ability to Drive and Use Machines
None reported

DRUG INTERACTIONS
Salbutamol (Ventolin®) and non-selective beta-blocking drugs, such as propranolol, should not usually be prescribed together.

Salbutamol (Ventolin®) is not contra-indicated in patients under treatment with monoamine oxidase inhibitors (MAOIs).

PREGNANCY AND LACTATION
Fertility
There is no information on the effects of salbutamol on human fertility. There were no adverse effects on fertility in animals (see Pre-clinical Safety Data).

Pregnancy
Administration of drugs during pregnancy should only be considered if the expected benefit to the mother is greater than any possible risk to the foetus. During worldwide marketing experience, rare cases of various congenital anomalies, including cleft palate and limb defects have been reported in the offspring of patients being treated with salbutamol. Some of the mothers were taking multiple medications during their pregnancies. As no consistent pattern of defects can be discerned, and baseline rate for congenital anomalies is 2 to 3%, a relationship with salbutamol use cannot be established.

Lactation
As salbutamol is probably secreted in breast milk its use in nursing mothers is not recommended unless the expected benefits outweigh any potential risk. It is not known whether salbutamol in breast milk has a harmful effect on the neonate.

ADVERSE EFFECTS
Adverse reactions are listed below by system organ class and frequency. Frequencies are defined as: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1000 to <1/100), rare (≥1/10,000 to <1/1000) and very rare (<1/10,000) including isolated reports. Very common and common reactions were generally determined from clinical trial data. Rare and very rare reactions were generally determined from spontaneous data.

immune system disorders
Very rare: Hypersensitivity reactions including angioedema, urticaria, bronchospasm, hypotension and collapse.

Metabolism and nutrition disorders
Rare: Hypokalaemia.

Potentially serious hypokalaemia may result from beta-2 agonist therapy.

Nervous system disorders
Very common: Tremor.
Common: Headache.
Very rare: Hyperactivity.

Cardiac disorders
Common: Tachycardia, palpitations.
Rare: Cardiac arrhythmias including atrial fibrillation, supraventricular tachycardia and extrasystoles.

Vascular disorders
Rare: Peripheral vasodilatation.

Musculoskeletal and connective tissue disorders
Common: Muscle cramps.
Very rare: Feeling of muscle tension.

OVERDOSAGE AND TREATMENT
The most common signs and symptoms of overdose with Salbutamol (Ventolin®) are transient beta agonist pharmacologically mediated events (see Warnings and Precautions and Adverse Reactions). Hypokalaemia may occur following overdose with Salbutamol (Ventolin®). Serum potassium levels should be monitored.
Lactic acidosis has been reported in association with high therapeutic doses as well as overdoses of short-acting beta-agonist therapy, therefore monitoring for elevated serum lactate and consequent metabolic acidosis (particularly if there is persistence or worsening of tachypnea despite resolution of other signs of bronchospasm such as wheezing) may be indicated in the setting of overdose.

Nausea, vomiting and hyperglycaemia have been reported, predominantly in children and when salbutamol overdose has been taken via the oral route.

**Treatment**

Further management should be as clinically indicated or as recommended by the national poisons centre, where available.

**STORAGE CONDITIONS**

Store at temperatures not exceeding 30°C.

**AVAILABILITY**

Salbutamol (Ventolin®) 2mg Tablet: 10 tablets per foil strip (box of 100s).

**CAUTION**

Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

Keep all medicines out of reach of children.

VENTOLIN is a registered trademark of the GlaxoSmithKline group of companies ©2014, GlaxoSmithKline. All rights reserved.

Version number: GDS21/IPI06 Revision date: 05 Feb 2014
Salbutamol sulphate

Ventolin®

2mg/5mL Syrup
Anti-asthma

PRODUCT DESCRIPTION
Salbutamol (Ventolin®) 2mg/5mL Syrup, orange flavour: Each 5mL of orange flavoured, orange-coloured, sugar-free syrup contains 2mg Salbutamol (as sulfate).

PHARMACOLOGIC PROPERTIES

Pharmacodynamics
Salbutamol is a selective beta-2 adrenoceptor agonist. At therapeutic doses it acts on the beta-2 adrenoceptors of bronchial muscle providing short acting (4 to 6 hour) bronchodilation in reversible airways obstruction.

Pharmacokinetics
Salbutamol administered intravenously has a half-life of 4 to 6 hours and is cleared partly renally and partly by metabolism to the inactive 4'-0- sulphate (phenolic sulphate) which is also excreted primarily in the urine. The faeces are a minor route of excretion. The majority of a dose of salbutamol given intravenously, orally or by inhalation is excreted within 72 hours. Salbutamol is bound to plasma proteins to the extent of 10%.

After oral administration, salbutamol is absorbed from the gastrointestinal tract and undergoes considerable first-pass metabolism to the phenolic sulphate. Both unchanged drug and conjugate are excreted primarily in the urine. The bioavailability of orally administered salbutamol is about 50%.

Pre-clinical Safety Data
In common with other potent selective beta-2 receptor agonists, salbutamol has been shown to be teratogenic in mice when given subcutaneously. In a reproductive study, 9.3% of foetuses are found to have cleft palate, at 2.5mg/kg, 4 times the maximum human oral dose. In rats, treatment at the levels of 0.5, 2.32, 10.75 and 50mg/kg/day orally throughout pregnancy resulted in no significant foetal abnormalities. The only toxic effect was an increase in neonatal mortality at the highest dose level as the result of lack of maternal care. A reproductive study in rabbits revealed cranial malformations in 37% of foetuses at 50mg/kg/day, 78 times the maximum human oral dose.

Reproduction studies in rats demonstrated no evidence of impaired fertility at oral doses of Salbutamol (Ventolin®) up to 50 mg/kg.

INDICATIONS
Salbutamol (Ventolin®) is a selective beta-2 adrenoceptor agonist indicated for the treatment or prevention of bronchospasm. It provides short acting bronchodilation in reversible airways obstruction due to asthma, chronic bronchitis and emphysema.

Bronchodilators should not be the only or main treatment in patients with persistent asthma. In patients with persistent asthma unresponsive to Salbutamol (Ventolin®), treatment with inhaled corticosteroids is recommended to achieve and maintain control. Failing to respond to treatment with Salbutamol (Ventolin®) may signal a need for urgent medical advice or treatment.

Salbutamol (Ventolin®) syrup is indicated for the relief of bronchospasm in bronchial asthma of all types, chronic bronchitis and emphysema.

Salbutamol (Ventolin®) Syrup is suitable oral therapy for children or those adults who prefer liquid medicines.

DOSE AND ADMINISTRATION
Salbutamol (Ventolin®) has a duration of action of 4 to 6 hours in most patients. Increasing use of beta-2 agonists may be a sign of worsening asthma.

Under these conditions a reassessment of the patient's therapy plan may be required and concomitant glucocorticosteroid therapy should be considered.

As there may be adverse effects associated with excessive dosing, the dosage or frequency of administration should only be increased on medical advice.

- **Adults**
  
  The usual effective dose is 10ml salbutamol (4 mg of salbutamol) 3 or 4 times per day. If adequate bronchodilation is not obtained each single dose may be gradually increased to as much as 20ml of syrup (8 mg salbutamol).

  Some patients obtain adequate relief with 5 ml of syrup (2 mg salbutamol) 3 or 4 times daily.

- **Children**
  
  2-6 years 2.5 to 5ml of syrup (1 to 2 mg salbutamol) 3 or 4 times daily.

  6-12 years 5ml of syrup (2 mg salbutamol) 3 or 4 times daily.

  Over 12 years 5 to 10ml of syrup (2 to 4 mg salbutamol) 3 or 4 times daily.

- **Special patient groups**
  
  In elderly patients or in those known to be unusually sensitive to beta-adrenergic stimulant drugs, it is advisable to initiate treatment with 5ml of syrup (2 mg salbutamol) 3 or 4 times per day.

CONTRAINdications
Salbutamol (Ventolin®) Syrup is contraindicated in patients with a history of hypersensitivity to any of its components. Non-i.v. formulations of Salbutamol (Ventolin®) must not be used to arrest uncomplicated premature labour or threatened abortion.

WARNINGS AND PRECAUTIONS
The management of asthma should normally follow a stepwise programme, and patient response should be monitored clinically and by lung function tests. Increasing use of short-acting inhaled beta-2 agonists to control symptoms indicates deterioration of asthma control. Under these conditions, the patient's therapy plan should be reassessed. Sudden and progressive deterioration in asthma control is potentially life threatening and consideration...
should be given to starting or increasing corticosteroid therapy. In patients considered at risk, daily peak flow
monitoring may be instituted. Patients should be warned that if either the usual relief is diminished or the usual duration of action reduced, they
should not increase the dose or its frequency of administration, but should seek medical advice.
Salbutamol (Ventolin®) should be administered cautiously to patients with thyrotoxicosis.
Potentially serious hypokalaemia may result from beta2 agonist therapy mainly from parenteral and nebulised
administration. Particular caution is advised in acute severe asthma as this effect may be potentiated by concomitant
treatment with xanthine derivatives, steroids, diuretics and by hypoxia. It is recommended that serum potassium
levels are monitored in such situations.
In common with other beta-adrenoceptor agonists, Salbutamol (Ventolin®) can induce reversible metabolic changes,
for example increased blood sugar levels. The diabetic patient may be unable to compensate for this and the
development of ketaciddosis has been reported. Concurrent administration of corticosteroids can exaggerate this
effect.
Long term treatment with Salbutamol (Ventolin®) Syrup (Sugar-containing formulation) increases the risk of dental
caries. It is important that adequate dental hygiene is maintained.

Effects on Ability to Drive and Use Machines
None Reported.

DRUG INTERACTIONS
Salbutamol (Ventolin®) and non-selective beta-blocking drugs, such as propranolol, should not usually be prescribed
together.
Salbutamol (Ventolin®) is not contraindicated in patients under treatment with monoamine oxidase inhibitors (MAOIs).

PREGNANCY AND LACTATION
Fertility
There is no information on the effects of salbutamol on human fertility. There were no adverse effects on fertility in animals (see Pre-clinical Safety Data).
Pregnancy
Administration of drugs during pregnancy should only be considered if the expected benefit to the mother is greater
than any possible risk to the foetus. During worldwide marketing experience, rare cases of various congenital anomalies, including cleft palate and limb
defects have been reported in the offspring of patients being treated with salbutamol. Some of the mothers were
taking multiple medications during their pregnancies. As no consistent pattern of defects can be discerned, and baseline rate for congenital anomalies is 2 to 3%, a
relationship with salbutamol use cannot be established.
Lactation
As salbutamol is probably secreted in breast milk its use in nursing mothers is not recommended unless the expected
benefits outweigh any potential risk. It is not known whether salbutamol in breast milk has a harmful effect on the
neonate.

ADVERSE EFFECTS
Adverse reactions are listed below by system organ class and frequency. Frequencies are defined as: very common
(≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1000 to <1/100), rare (≥1/10,000 to <1/1000) and very rare
(<1/10,000) including isolated reports. Very common and common reactions were generally determined from clinical
trial data. Rare and very rare reactions were generally determined from spontaneous data.

Immune system disorders
Very rare: Hypersensitivity reactions including angioedema, urticaria, bronchospasm, hypotension and collapse.

Metabolism and nutrition disorders
Rare: Hypokalaemia.
Potentially serious hypokalaemia may result from beta2 agonist therapy.

Nervous system disorders
Common: Tremor.

Cardiac disorders
Common: Tachycardia, palpitations.

Vascular disorders
Rare: Peripheral vasodilatation.

Musculoskeletal and connective tissue disorders
Common: Muscle cramps.

OVERDOSAGE AND TREATMENT
The most common signs and symptoms of overdose with Salbutamol (Ventolin®) are transient beta agonist
pharmacologically mediated events (see Warnings and Precautions and Adverse Reactions).
Hyypokalaemia may occur following overdose with Salbutamol (Ventolin®). Serum potassium levels should be
monitored.
Lactic acidosis has been reported in association with high therapeutic doses as well as overdoses of short-acting
beta-agonist therapy, therefore monitoring for elevated serum lactate and consequent metabolic acidosis (particularly
if there is persistence or worsening of tachypnea despite resolution of other signs of bronchospasm such as
wheezing) may be indicated in the setting of overdose.
Nausea, vomiting and hyperglycaemia have been reported, predominantly in children and when Salbutamol (Ventolin®) overdose has been taken via the oral route.

**Treatment**
Further management should be as clinically indicated or as recommended by the national poisons centre, where available.

**Incompatibilities**
Salbutamol (Ventolin®) Syrup, orange flavour (Sugar-free formulation):
Dilution of Salbutamol (Ventolin®) Syrup with Syrup BP or Sorbitol solution is not recommended as this may result in precipitation of the cellulose thickening agent.

**STORAGE CONDITION**
Salbutamol (Ventolin®) Syrup, orange flavour: Store below 30°C. Protect from light.

**INSTRUCTIONS FOR USE/HANDLING**

**Dilution:**
Salbutamol (Ventolin®) Syrup, orange flavour (Sugar-free formulation):
May be diluted with Purified Water BP (50% v/v). The resulting mixture should be protected from light and used within 28 days.
A 50% v/v dilution of Salbutamol (Ventolin®) Syrup has been shown to be adequately preserved against microbial contamination. However, to avoid the possibility of introducing excessive microbial contamination, the Purified Water used for dilution should be recently prepared or alternatively it should be boiled and cooled immediately before use.
Admixture of Salbutamol (Ventolin®) Syrup with other liquid preparation is not recommended.

**AVAILABILITY**
Salbutamol (Ventolin®) 2mg/5mL syrup, orange flavour: Bottles of 60mL

**CAUTION**
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.
Keep all medicines out of reach of children.

VENTOLIN is a registered trademark of the GlaxoSmithKline group of companies ©2014, GlaxoSmithKline. All rights reserved.

Version number: GDS21/PI05 Revision date: 05 February 2014

Mfd by:
SmithKline Beecham
Don Celso Tuason Avenue, Cainta, Rizal, Philippines
for
GlaxoSmithKline Philippines Inc
2286 Chino Roces Avenue, City of Makati
Tel. 892-0761
How to use your VENTOLIN™ ROTAHALER™

1. Pull the 2 halves apart and throw away the empty capsule.
2.arasikana kug'iyera muhika hikurikira n’iminwa. Humeka rimwe vyihuse, impwemu ndende unyujije ku kanwa.
3. Place the white end in your mouth and exhale.
4. Sostenga el extremo blanco con una mano y pegare el extremo azul del ROTAHALER.
5. Pegang ROTAHALER menjauh dari mulut. Buang napas.
6. Colóquese el extremo blanco del ROTAHALER™ en la boca, entre los labios.
7. Pegang bagian putih dan putar bagian biru sejauh mungkin.
8. Pegang the white end vertically, baguette above.
10. Pegang the white end horizontally, baguette over.

For your next dose:
1. Place the white end in your mouth again and exhale.
2. Sostenga el extremo blanco del ROTAHALER™ en la boca, entre los labios.
3. Pegang bagian putih dan putar bagian biru sejauh mungkin.
4. Pegang the white end horizontally, baguette over.
5. Pegang the white end vertically, baguette above.
6. Pegang the white end horizontally, baguette over.

The capsule should be pushed clear end first until moulded line is seen.

• Make sure you have removed both parts of the capsule before taking your next dose.

Replace your ROTAHALER™ after 6 months.

How to clean your VENTOLIN ROTAHALER™

1. Remove the ROTAHALER™ & ROTACAPS™.
2. Ventolin United Kingdom-Sovrin-Slough 1-2-4 zilizo hapo juu.
3. Cambodge-KHM; 2-4 zilizo hapo juu.
Sika ebitundu by’akacupa ebibiri osuule kapiso. Kakasa nti ojeemu ebitundu by’akapiso ebibiri nga tonaddamu kufuna ddagala ddala.

Omusawo wo bwaba akugambye okukozesa bu kapiso obubiri yisaawo obutikitiki 30 nga tonaddamu kozesa kasanduuko kalala ngoyita mitendera 2-4 waggulu.

Olongoosa otya akacupa ke ddagala ly’asima?

Kuuma akacupa nga kayonjo era nga kakalu obudde bwonna era kajje ewali ebugumu enng1

Longoosa akacupa ko buli luvanyuma lwa sabiiti biri • Sika ebitundu by’akacupa ebibiri era okasuuke kapiso eweddemu.
• Yozza ebitundu ebyo ebibiri mu mazzi agabuguma era obikazze bulungi nga tonabizaawo

Funna akacupa akalala oluvanyuma lw’e myezi 6.

Glaxo Wellcome GmbH & Co. KG
Industriestraβe 32-36
23843 Bad Oldesloe
Germany

VENTOLIN, ROTACAPS and ROTAHALER are trade marks of the GSK group of companies.

© 2014 GSK group of companies. All rights reserved.
Salbutamol (as sulfate) Rotacap®: Each Rotacap® contains a mixture of 200mcg microfine salbutamol sulfate and large particle lactose (which contains milk protein) in hard gelatin cartridges.

PHARMACOLOGIC PROPERTIES

Pharmacodynamics
Salbutamol is a selective beta2-adrenoceptor agonist. At therapeutic doses it acts on the beta2-adrenoceptors of bronchial muscle providing short acting (4 to 6 hour) bronchodilation with a fast onset (within 5 minutes) in reversible airways obstruction.

Pharmacokinetics
Absorption
After administration by the inhaled route between 10 and 20% of the dose reaches the lower airways. The remainder is retained in the delivery system or is deposited in the oropharynx from where it is swallowed. The fraction deposited in the airways is absorbed into the pulmonary tissues and circulation but is not metabolised by the lung.

Distribution
Salbutamol is bound to plasma proteins to the extent of 10%.

Metabolism
On reaching the systemic circulation, salbutamol becomes accessible to hepatic metabolism and is excreted, primarily in the urine, as unchanged drug and as the phenolic sulphate.

The swallowed portion of an inhaled dose is absorbed from the gastrointestinal tract and undergoes considerable first-pass metabolism to the phenolic sulphate. Both unchanged drug and conjugate are excreted primarily in the urine.

Elimination
Salbutamol administered intravenously has a half-life of four to six hours and is cleared partly renally and partly by metabolism to the inactive 4’-O-sulphate (phenolic sulphate) which is also excreted primarily in the urine. The faeces are a minor route of excretion. The majority of a dose of salbutamol given intravenously, orally or by inhalation is excreted within 72 hours.

Pre-clinical Safety Data
In common with other potent selective beta-2 receptor agonists, salbutamol has been shown to be teratogenic in mice when given subcutaneously. In a reproductive study, 9.3% of foetuses were found to have cleft palate, at 2.5 mg/kg, four times the maximum human oral dose. In rats, treatment at the levels of 0.5, 2.32, 10.75 and 50mg/kg/day orally throughout pregnancy resulted in no significant foetal abnormalities. The only toxic effect was an increase in neonatal mortality at the highest dose level as the result of lack of maternal care. A reproductive study in rabbits revealed cranial malformations in 37% of foetuses at 50mg/kg/day, 78 times the maximum human oral dose.

In an oral fertility and general reproductive performance study in rats at doses of 2 and 50 mg/kg/day, with the exception of a reduction in number of weanlings surviving to day 21 post partum at 50 mg/kg/day, there were no adverse effects on fertility, embryofetal development, litter size, birth weight or growth rate.

INDICATIONS
Salbutamol is a selective beta2 adrenoceptor agonist indicated for the treatment or prevention of bronchospasm. It provides short acting (four hours) bronchodilation in reversible airways obstruction due to asthma, chronic bronchitis and emphysema. For patients with asthma salbutamol may be used to relieve symptoms when they occur and to prevent them prior to a known trigger.

Bronchodilators should not be the only or main treatment in patients with persistent asthma. In patients with persistent asthma unresponsive to Salbutamol (Ventolin®), treatment with inhaled corticosteroids is recommended to achieve and maintain control. Failing to respond to treatment with Salbutamol (Ventolin®) may signal a need for urgent medical advice or treatment.

DOSAGE AND ADMINISTRATION
Salbutamol (Ventolin®) has a duration of action of 4 to 6 hours in most patients. Increasing use of beta2 agonists may be a sign of worsening asthma. Under these conditions a reassessment of the patient's therapy plan may be required and concomitant glucocorticosteroid therapy should be considered.

As there may be adverse effects associated with excessive dosing, the dosage or frequency of administration should only be increased on medical advice.

Salbutamol (Ventolin®) Rotacaps® capsules are for inhalation use only, using a VENTOLIN® ROTAHALER® inhaler.

RELIEF OF ACUTE BRONCHOSPASM
- Adults
  200 or 400 micrograms.
- Children
  200 micrograms.

PREVENTION OF ALLERGEN OR EXERCISE-INDUCED BRONCHOSPASM
- Adults
400 micrograms before challenge or exertion.
- **Children**
  200 micrograms before challenge or exertion.

**CHRONIC THERAPY**
- **Adults**
  400 micrograms 3 or 4 times daily
- **Children**
  200 micrograms 3 or 4 times daily.

On demand use of Salbutamol (Ventolin®) should not exceed four times daily. Reliance on such supplementary use or a sudden increase in dose indicates deteriorating asthma (see **Warnings and Precautions**)

**CONTRAINDICATIONS**
Salbutamol (Ventolin®) is contraindicated in patients with a history of hypersensitivity to any of its components (see **Excipients**). Non-i.v. formulations of VENTOLIN must not be used to arrest uncomplicated premature labour or threatened abortion.
Salbutamol (Ventolin®) dry powder inhaler formulations are contraindicated in patients with severe milk-protein allergy or who have a history of hypersensitivity to salbutamol or any of its formulation components (see **Excipients**).

**WARNINGS AND PRECAUTIONS**
The management of asthma should normally follow a stepwise programme, and patient response should be monitored clinically and by lung function tests.
Increasing use of short-acting bronchodilators, in particular beta-2 agonists to relieve symptoms indicates deterioration of asthma control. Under these conditions, the patient's therapy plan should be reassessed.
Sudden and progressive deterioration in asthma control is potentially life-threatening and consideration should be given to starting or increasing corticosteroid therapy. In patients considered at risk, daily peak flow monitoring may be instituted.
Salbutamol should be administered cautiously to patients with thyrotoxicosis.
Potentially serious hypokalaemia may result from beta-2 agonist therapy mainly from parenteral and nebulised administration.
Particular caution is advised in acute severe asthma as this effect may be potentiated by concomitant treatment with xanthine derivatives, steroids, diuretics and by hypoxia. It is recommended that serum potassium levels are monitored in such situations.
As with other inhalation therapy, paradoxical bronchospasm may occur, resulting in an immediate increase in wheezing after dosing. This should be treated immediately with an alternative presentation or a different fast-acting inhaled bronchodilator, if immediately available. The specific salbutamol presentation should be discontinued, and if necessary a different fast-acting bronchodilator instituted for ongoing use.
In the event of a previously effective dose of inhaled salbutamol failing to give relief for at least three hours, the patient should be advised to seek medical advice in order that any necessary additional steps may be taken.

**DRUG INTERACTIONS**
Salbutamol (Ventolin®) and non-selective beta-blocking drugs, such as propranolol, should not usually be prescribed together.
Salbutamol is not contra-indicated in patients under treatment with monoamine oxidase inhibitors (MAOIs).

**PREGNANCY AND LACTATION**
**Fertility**
There is no information on the effects of salbutamol on human fertility. There were no adverse effects on fertility in animals (see **Pre-clinical Safety Data**).
**Pregnancy**
Administration of drugs during pregnancy should only be considered if the expected benefit to the mother is greater than any possible risk to the foetus.
During worldwide marketing experience, rare cases of various congenital anomalies, including cleft palate and limb defects have been reported in the offspring of patients being treated with salbutamol. Some of the mothers were taking multiple medications during their pregnancies. As no consistent pattern of defects can be discerned, and baseline rate for congenital anomalies is 2 to 3%, a relationship with salbutamol use cannot be established.
**Lactation**
As salbutamol is probably secreted in breast milk, its use in nursing mothers is not recommended unless the expected benefits outweigh any potential risk. It is not known whether salbutamol in breast milk has a harmful effect on the neonate.

**ADVERSE EFFECTS**
Adverse events are listed below by system organ class and frequency. Frequencies are defined as: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1000 to <1/100), rare (≥1/10,000 to <1/1000) and very rare (<1/10,000) including isolated reports. Very common and common events were generally determined from clinical trial data. Rare and very rare events were generally determined from spontaneous data.

**Immune system disorders**
Very rare:
- Hypersensitivity reactions including angioedema, urticaria, bronchospasm, hypotension and collapse

**Metabolism and nutrition disorders**
Rare:
- Hypokalaemia
Potentially serious hypokalaemia may result from beta₂ agonist therapy.

**Nervous system disorders**
- **Common:** Tremor, headache
- **Very rare:** Hyperactivity

**Cardiac disorders**
- **Common:** Tachycardia
- **Uncommon:** Palpitations
- **Very rare:** Cardiac arrhythmias including atrial fibrillation, supraventricular tachycardia and extrasystoles

**Vascular disorders**
- **Rare:** Peripheral vasodilatation

**Respiratory, thoracic and mediastinal disorders**
- **Very rare:** Paradoxical bronchospasm

**Gastrointestinal disorders**
- **Uncommon:** Mouth and throat irritation

**Musculoskeletal and connective tissue disorders**
- **Uncommon:** Muscle cramps

**OVERDOSAGE AND TREATMENT**

The most common signs and symptoms of overdose with Salbutamol (Ventolin®) are transient beta agonist pharmacologically mediated events (see Warnings and Precautions and Adverse Reactions). Hypokalaemia may occur following overdosage with Salbutamol (Ventolin®). Serum potassium levels should be monitored.

Lactic acidosis has been reported in association with high therapeutic doses as well as overdoses of short-acting beta-agonist therapy, therefore monitoring for elevated serum lactate and consequent metabolic acidosis (particularly if there is persistence or worsening of tachypnea despite resolution of other signs of bronchospasm such as wheezing) may be indicated in the setting of overdose.

**STORAGE CONDITION**

To keep the Rotacap® in good condition it is important that they are stored in a dry place and where they will not be exposed to extremes of temperature and should be stored below 30°C.

**INSTRUCTIONS FOR USE/HANDLING**

The Rotacap® must only be inserted in to the Rotahaler® immediately prior to use. Failure to observe this instruction will affect the delivery of the drug.

**AVAILABILITY**

Salbutamol (Ventolin®) Rotacap® 200mcg: Box of 10’s and 128’s

**CAUTION**

Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription. Keep all medicines out of reach of children.

VENTOLIN, ROTACAP and ROTAHALER are registered trademarks of the GlaxoSmithKline group of companies. ©2013, GlaxoSmithKline. All rights reserved.

Version number: GDS25/IP107 Revision date: 14 April 2014
Salbutamol 200mcg and lactose in a gelatine capsule

Salbutamol (Ventolin®) Rotacap® helps to open up the airways in your lungs, making it easier for you to breathe. It helps to relieve chest tightness, wheezing and cough associated with asthma and is used to treat breathing problems in people with asthma.

Do not use Salbutamol (Ventolin®) Rotacap® if you are allergic (hypersensitive) to salbutamol sulfate, any of the other ingredients or have a severe allergy to milk proteins.

If you are pregnant, planning to become pregnant or breast feeding, talk to your doctor before taking Salbutamol (Ventolin®) Rotacap®.

BEFORE USE: Tell your doctor if you have an overactive thyroid gland, low blood potassium or if you are taking other medicines including beta-blockers for high blood pressure or a heart condition.

USE: Salbutamol (Ventolin®) Rotacap® capsules must only be used by inhalation from a VENTOLIN® ROTAHALER® – Do not swallow.

Adults: The starting dose is one to two inhalations (200-400mcg) once a day. The maximum dose is two inhalations (400mcg) four times a day.

Children: The starting dose is one inhalation (200mcg) once a day. The maximum dose is one inhalation (200mcg) four times a day.

Contact your doctor if you take too much Salbutamol (Ventolin®).

Tell your doctor if your Salbutamol (Ventolin®) does not seem to be working as well as usual or if the effects last for less than 3 hours, as your chest problem may be getting worse and you may need a different medicine.

If your breathing or wheezing gets worse straight after using Salbutamol (Ventolin®) Rotacap®, stop using it, and contact your doctor immediately.

SIDE EFFECTS: The most common side effects are feeling shaky, headache and heart beating faster. Uncommon side effects are irregular heart beat (palpitations), mouth & throat irritation and muscle cramps. Rare side effects are low blood potassium level and increased blood flow to the extremities (widening of the blood vessels). Very rare side effects are feeling unusually restless or excitable and allergic reactions (skin rash, swelling of face/mouth, increased breathlessness or collapse). If you have an allergic reaction or other severe side effects contact your doctor immediately.

STORAGE: Do not store above 30°C. Store in a dry place. Keep out of reach of children.

Revision date: 14 April 2014
Salbutamol 200mcg at lactose sa isang kapsulang gelatine.

Ang Salbutamol (Ventolin®) Rotacap® ay tumutulong para buksan ang mga daanan ng hangin sa baga, para maging mas maginhawa ang paghinga. Tumutulong itong paghingawhin ang paninikip ng dibdib, huni sa paghinga at ubong kauaunay ng hika at ginagamit ito para gamutin ang mga problema sa paghinga ng mga taong may hika.

Huwag gagamitin ang Salbutamol (Ventolin®) Rotacap® kung kayo ay allergic (sobrang sensitibo) sa salbutamol sulfate o alinman sa ibang mga sangkap o kung kayo ay may matinding allergy sa mga protina ng gatas.

Kung kayo ay buntis, nagbabalak magbuntis o magpasuso, kausapin muna ang doktor ninyo bago gumamit ng Salbutamol (Ventolin®) Rotacap®.

BAGO GAMITIN: Sabihin sa doktor ninyo kung kayo ay may sobrang aktibong thyroid gland, mababang potassium sa dugo o kung gumagamit kayo ng ibang mga gamot kabilang na ang beta-blockers para sa alta presyon o problema sa puso.

PAGGAMIT: Ang mga kapsula ng Salbutamol (Ventolin®) Rotacap® ay ginagamit lamang sa pamamagitan ng paghigop o inhalation mula sa isang VENTOLIN® ROTAHALER® – Huwag lulunukin ang kapsula.

Mga taong nasa hustong gulang: Ang panimulang dosis ay isa hanggang dalawang paghigop (200-400mcg) minsan sa isang araw. Ang pinakamalabang paninikip ay 400mcg (400mcg) apar na beses sa isang araw. Ang mga bata: Ang panimulang dosis ay isang paghigop (200mcg) minsan sa isang araw. Ang pinakamalabang paninikip ay 400mcg (400mcg) apar na beses sa isang araw.

Kontakin ang doktor ninyo kung nakagamit kayo ng sobrang daming Salbutamol (Ventolin®).

Sabiin sa doktor ninyo kung ang Salbutamol (Ventolin®) ninyo ay parang hindi gumagana nang kasinghusay ng karaniwang epekto ay tumatagal nang kulang sa 3 oras, dahil maaaring ang problema ninyo sa dibdib ay dito sa labas ng puso.

Kung ang paninikip o paghigop ng dibdib ay lumalabas sa karaniwang epekto, kontakin ang inyong doktor.

MGA DI-KANAI-NAIS NA EPEKTO O SIDE EFFECTS: Ang pinakakaraniwang side effects ay pakiramdam na mabubuway, pananakit na ulo at mas mabilis na pagtibok ng puso. Ang hindi karaniwang side effects ay hindi regular na pagtibok ng puso, iritasyon sa bibig at lalamunan at papalitik at ng mga kalamnan. Ang bihirang side effects ay mas malakas na pagduloy ng dugo o extremities (pagluwang ng mga uga). Ang napakabihirang side effects ay hindi karanibang pakiramdam na hindi magiging makalalang at maaaring lumulubad na allergic na reaksiyon (singaw sa balat, pamamaga ng mukha/bibig, mas malalang pagdalog na pagkatumba [collapse]). Kung kayo ay may allergic na reaksiyon o ibang matilig na side effects, kontakin ang doktor.

PAGTATAGO: Itago sa temperaturang hindi lalagpas sa 30°C sa isang tuyong lugar. Itago sa hindi maabot ng mga bata.

Petsa ng version: 14 Abril 2014
Salbutamol
Ventolin® Nebules®
1mg/mL Solution for Inhalation
Anti-asthma

PRODUCT DESCRIPTION
Salbutamol (Ventolin® Nebules®) Solution for Inhalation 1mg/mL is in a plastic ampoule containing a concentration of salbutamol of 0.1% (1mg salbutamol, as the sulphate, in 1mL). Each Salbutamol (Ventolin® Nebules®) Solution for Inhalation contains 2.5mL of solution equivalent to 2.5mg salbutamol.

PHARMACOLOGIC PROPERTIES
Pharmacodynamics
Salbutamol is a selective beta2-adrenoceptor agonist. At therapeutic doses it acts on the beta2-adrenoceptors of bronchial muscle providing short acting (4 to 6 hour) bronchodilation with a fast onset (within 5 minutes) in reversible airways obstruction.

Pharmacokinetics
Absorption
After administration by the inhaled route, between 10 and 20% of the dose reaches the lower airways. The remainder is retained in the delivery system or is deposited in the oropharynx from where it is swallowed. The fraction deposited in the airways is absorbed into the pulmonary tissues and circulation but is not metabolised by the lung.

Distribution
Salbutamol is bound to plasma proteins to the extent of 10%.

Metabolism
On reaching the systemic circulation it becomes accessible to hepatic metabolism and is excreted, primarily in the urine, as unchanged drug and as the phenolic sulphate.

The swallowed portion of an inhaled dose is absorbed from the gastrointestinal tract and undergoes considerable first-pass metabolism to the phenolic sulphate. Both unchanged drug and conjugate are excreted primarily in the urine.

Elimination
Salbutamol administered intravenously has a half-life of four to six hours and is cleared partly renally and partly by metabolism to the inactive 4'-O-sulphate (phenolic sulphate) which is also excreted primarily in the urine. The faeces are a minor route of excretion. The majority of a dose of salbutamol given intravenously, orally or by inhalation is excreted within 72 hours.

Pre-clinical Safety Data
In common with other potent selective beta2 receptor agonists, salbutamol has been shown to be teratogenic in mice when given subcutaneously. In a reproductive study, 9.3% of foetuses were found to have cleft palate, at 2.5 mg/kg, 4 times the maximum human oral. In rats, treatment at the levels of 0.5, 2.32, 10.75 and 50mg/kg/day orally throughout pregnancy resulted in no significant foetal abnormalities. The only toxic effect was an increase in neonatal mortality at the highest dose level as the result of lack of maternal care. A reproductive study in rabbits revealed cranial malformations in 37% of foetuses at 50mg/kg/day, 78 times the maximum human oral dose.

INDICATIONS
Salbutamol is a selective beta2 adrenoreceptor agonist indicated for the treatment or prevention of bronchospasm. It provides short acting (four hours) bronchodilation in reversible airways obstruction due to asthma, chronic bronchitis and emphysema. For patients with asthma salbutamol may be used to relieve symptoms when they occur and to prevent them prior to a known trigger.

Bronchodilators should not be the only or main treatment in patients with persistent asthma. In patients with persistent asthma unresponsive to Salbutamol (Ventolin®), treatment with inhaled corticosteroids is recommended to achieve and maintain control. Failing to respond to treatment with Salbutamol (Ventolin®) may signal a need for urgent medical advice or treatment.

Salbutamol (Ventolin® Nebules®) are indicated for the routine management of chronic bronchospasm (unresponsive to conventional therapy) and treatment of acute severe asthma (status asthmaticus).

DOSAGE AND ADMINISTRATION
Salbutamol (Ventolin®) has a duration of action of 4 to 6 hours in most patients.
Salbutamol (Ventolin® Nebules®) are intended to be used undiluted. However, if prolonged delivery time is desirable (more than 10 minutes) dilution using sterile normal saline as a diluent may be required.
Salbutamol (Ventolin® Nebules®) are to be used with a nebuliser, under the direction of a physician.

The solution must not be injected, or swallowed.
Increasing use of beta2 agonists may be a sign of worsening asthma. Under these conditions a reassessment of the patient's therapy plan may be required and concomitant glucocorticosteroid therapy should be considered.

Delivery of the aerosol may be by facemask, 'T' piece or via an endotracheal tube. Intermittent positive pressure ventilation may be used but is rarely necessary. When there is a risk of anoxia through hypoventilation, oxygen should be added to the inspired air.

As there may be adverse effects associated with excessive dosing, the dosage or frequency of administration should only be increased on medical advice.
As many nebulisers operate on a continuous flow basis, it is likely that nebulised drug will be released in the local environment. Salbutamol (Ventolin® Nebules®) should therefore be administered in a well ventilated room, particularly in hospitals when several patients may be using nebulisers in the same space at the same time.

- **Adults and Children**
  A suitable starting dose of salbutamol by wet inhalation is 2.5 milligrams. This may be increased to 5 milligrams. Treatment may be repeated four times daily. In adults higher dosing, up to 40 milligrams per day, can be given under strict medical supervision in hospital for the treatment of severe airways obstruction.

  Clinical efficacy of nebulised Salbutamol (Ventolin®) in infants under 18 months is uncertain. As transient hypoxaemia may occur, supplemental oxygen therapy should be considered.

**CONTRAINDICATIONS**
Salbutamol (Ventolin® Nebules®) are contraindicated in patients with a history of hypersensitivity to any of their components.

Non-i.v. formulations of VENTOLIN must not be used to arrest uncomplicated premature labour or threatened abortion.

**WARNINGS AND PRECAUTIONS**

The management of asthma should normally follow a stepwise programme, and patient response should be monitored clinically and by lung function tests.

Increasing use of short-acting inhaled beta2 agonists to control symptoms indicates deterioration of asthma control. Under these conditions, the patient’s therapy plan should be reassessed. Sudden and progressive deterioration in asthma control is potentially life threatening and consideration should be given to starting or increasing corticosteroid therapy. In patients considered at risk, daily peak flow monitoring may be instituted.

Salbutamol (Ventolin® Nebules®) must only be used by inhalation, to be breathed in through the mouth, and must not be injected or swallowed.

Patients receiving treatment at home with Salbutamol (Ventolin® Nebules®) must be warned that if either the usual relief is diminished or the usual duration of action reduced, they should not increase the dose or its frequency of administration, but should seek medical advice.

Salbutamol (Ventolin® Nebules®) should be used with caution in patients known to have received large doses of other sympathomimetic drugs.

Salbutamol (Ventolin®) should be administered cautiously to patients with thyrotoxicosis.

A small number of cases of acute angle closure glaucoma have been reported in patients treated with a combination of nebulised Salbutamol (Ventolin®) and ipratropium bromide. A combination of nebulised Salbutamol (Ventolin®) with nebulised anticholinergics should therefore be used cautiously. Patients should receive adequate instruction in correct administration and be warned not to let the solution or mist enter the eye.

Potentially serious hypokalaemia may result from beta2 agonist therapy mainly from parenteral and nebulised administration. Partial caution is advised in acute severe asthma as this effect may be potentiated by concomitant treatment with xanthine derivatives, steroids, diuretics and by hypoxia. It is recommended that serum potassium levels are monitored in such situations.

As with other inhalation therapy, paradoxical bronchospasm may occur, resulting in an immediate increase in wheezing after dosing. This should be treated immediately with an alternative presentation or a different fast-acting inhaled bronchodilator, if immediately available. Salbutamol (Ventolin® Nebules®) should be discontinued, and if necessary a different fast-acting bronchodilator instituted for ongoing use.

In common with other beta-adrenoceptor agonists, Salbutamol (Ventolin®) can induce reversible metabolic changes, for example increased blood sugar levels.

The diabetic patient may be unable to compensate for this and the development of ketoadidosis has been reported. Concurrent administration of corticosteroids can exaggerate this effect.

Lactic acidosis has been reported very rarely in association with high therapeutic doses of intravenous and nebulised short-acting beta-agonist therapy, mainly in patients being treated for an acute asthma exacerbation (see Adverse Reaction section). Increase in lactate levels may lead to dyspnoea and compensatory hyperventilation, which could be misinterpreted as a sign of asthma treatment failure and lead to inappropriate intensification of short-acting beta-agonist treatment. It is therefore recommended that patients are monitored for the development of elevated serum lactate and consequent metabolic acidosis in this setting.

**Effects on Ability to Drive and Use Machines**

None reported.

**DRUG INTERACTIONS**

Salbutamol (Ventolin®) and non-selective beta-blocking drugs, such as propranolol, should not usually be prescribed together.

Salbutamol (Ventolin®) is not contraindicated in patients under treatment with monoamine oxidase inhibitors (MAOIs).

**PREGNANCY AND LACTATION**

**Fertility**

There is no information on the effects of Salbutamol (Ventolin®) on human fertility. There were no adverse effects on fertility in animals (see Pre-clinical Safety Data).

**Pregnancy**

Administration of drugs during pregnancy should only be considered if the expected benefit to the mother is greater than any possible risk to the foetus.

During worldwide marketing experience, rare cases of various congenital anomalies, including cleft palate and limb defects have been reported in the offspring of patients being treated with salbutamol. Some of the mothers were taking multiple medications during their pregnancies.
As no consistent pattern of defects can be discerned, and baseline rate for congenital anomalies is 2-3%, a relationship with salbutamol use cannot be established.

**Lactation**

As salbutamol is probably secreted in breast milk, its use in nursing mothers is not recommended unless the expected benefits outweigh any potential risk. It is not known whether salbutamol in breast milk has a harmful effect on the neonate.

**ADVERSE EFFECTS**

Adverse events are listed below by system organ class and frequency. Frequencies are defined as: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1000 to <1/100), rare (≥1/10,000 to <1/1000) and very rare (<1/10,000) including isolated reports. Very common and common events were generally determined from clinical trial data. Rare and very rare events were generally determined from spontaneous data.

**Immune system disorders**

Very rare: Hypersensitivity reactions including angioedema, urticaria, bronchospasm, hypotension and collapse.

**Metabolism and nutrition disorders**

Rare: Hypokalaemia.

Potentially serious hypokalaemia may result from beta₂ agonist therapy.

Very rare: Lactic acidosis

Lactic acidosis has been reported very rarely in patients receiving intravenous and nebulised salbutamol therapy for the treatment of acute asthma exacerbation.

**Nervous system disorders**

Common: Tremor, headache

Very rare: Hyperactivity

**Cardiac disorders**

Common: Tachycardia

Uncommon: Palpitations

Very rare: Cardiac arrhythmias including atrial fibrillation, supraventricular tachycardia and extrasystoles

**Vascular disorders**

Rare: Peripheral vasodilatation

**Respiratory, thoracic and mediastinal disorders**

Very rare: Paradoxical bronchospasm

**Gastrointestinal disorders**

Uncommon: Mouth and throat irritation

**Musculoskeletal and connective tissue disorders**

Uncommon: Muscle cramps

**OVERDOSAGE AND TREATMENT**

The most common signs and symptoms of overdose with Salbutamol (Ventolin®) are transient beta agonist pharmacologically mediated events (see Warnings and Precautions and Adverse Reactions).

Hypokalaemia may occur following overdosage with Salbutamol (Ventolin®). Serum potassium levels should be monitored.

Lactic acidosis has been reported in association with high therapeutic doses as well as overdoses of short-acting beta-agonist therapy, therefore monitoring for elevated serum lactate and consequent metabolic acidosis (particularly if there is persistence or worsening of tachypnoea despite resolution of other signs of bronchospasm such as wheezing) may be indicated in the setting of overdose.

**STORAGE CONDITION**

Store below 30°C and protected from light.

**INSTRUCTIONS FOR USE AND HANDLING**

Dilution: Salbutamol (Ventolin® Nebules®) may be diluted with sterile normal saline.

Any unused solution in the chamber of the nebuliser must be discarded.

**AVAILABILITY**

Salbutamol (Ventolin® Nebules®) 1mg/mL Solution for Inhalation: 2.5mL Nebules in foil Blisters of 5 (Box of 30’s)

**CAUTION**

Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

Keep all medicines out of reach of children.

VENTOLIN and NEBULES are registered trademarks of the GlaxoSmithKline group of companies.

©2014, GlaxoSmithKline. All rights reserved.

Version number: GDS25/IPI09  Revision date: 14 April 2014
2. How the Ventolin Mini Spacer works

The Ventolin Mini Spacer fits on to your Ventolin Inhaler, the dose from the Ventolin Inhaler is sprayed into the Ventolin Mini Spacer from where it can be breathed easily into the lungs.

The Ventolin Mini Spacer has 3 main parts:

- The Mouthpiece Section with valve
- The Main Section
- The Extension

Detachable facemasks are available in small and medium sizes for young patients or those who are unable to inhale directly from the mouthpiece section.

3. How to Prepare the Ventolin Mini Spacer for use with the Ventolin Inhaler

- Ventolin Mini Spacer should be cleaned before it is used for the first time. See Section 6 (How to look after the Ventolin Mini Spacer) for full cleaning instructions.
- Make sure that the mouthpiece is firmly attached to the main section of the Ventolin Mini Spacer, as they may have come apart.
- Hold the main section of the Ventolin Mini Spacer and slide out the extension as far as it will go.
- Remove the cap from the Ventolin Inhaler and check inside it for any loose objects.
- Shake the Ventolin Inhaler well to ensure that the contents of the Ventolin Inhaler are well mixed.
- Remember to test that your Ventolin Inhaler is working by following the instructions provided with your Ventolin Inhaler. Point the Ventolin Inhaler canister away from you and press down on the top of the Ventolin Inhaler canister to release 2 puffs into the air.
- Push the Ventolin Inhaler mouthpiece firmly into the Ventolin Mini Spacer extension. The Ventolin Inhaler mouthpiece should fit snugly into the Ventolin Mini Spacer.
- If a facemask is being used, please follow the steps in Section 5 (How to use the Ventolin Mini Spacer with a facemask).

The Ventolin Mini Spacer and the Ventolin Inhaler are now ready to use. If a facemask is being used, please follow the steps in Section 5 (How to use the Ventolin Mini Spacer with a facemask).

4. How to use the Ventolin Mini Spacer with the Ventolin Inhaler

- Breathe out slowly as far as is comfortable to empty the lungs of air.
- Place the Ventolin Mini Spacer mouthpiece between your teeth and seal your lips around it.
- Press down on the top of the Ventolin Inhaler canister to release one puff into the Ventolin Mini Spacer.
- Then take a slow, deep breath in through the mouthpiece.
- Hold your breath in for several seconds or as long as is comfortable, while removing the Ventolin Mini Spacer mouthpiece from your mouth.
- Breathe out slowly, and then continue to breathe normally.
- If your doctor has told you to take two puffs, wait about 30 seconds before you take another puff by repeating the steps above.
- After use, remove the Ventolin Inhaler from the Ventolin Mini Spacer and replace the cap on the Ventolin Inhaler. If you have difficulty with slow deep breaths, an alternative way to use the Ventolin Mini Spacer is to keep your mouth tight on the mouthpiece of the Ventolin Mini Spacer and breathe slowly in and out 4 times after pressing down on the Ventolin Inhaler canister to release one puff. If your doctor has told you to take two puffs, wait about 30 seconds before you take another puff using this method.
- Tell your doctor or nurse or pharmacist if you are having difficulty using the Ventolin Mini Spacer.

5. How to use the Ventolin Mini Spacer and the Ventolin Inhaler with a facemask

Prepare the Ventolin Mini Spacer and Ventolin Inhaler as shown in Section 3 (How to prepare the Ventolin Mini Spacer and Ventolin Inhaler).

- Push the facemask onto the Ventolin Mini Spacer mouthpiece.
- Place the facemask over your mouth and nose, making sure there are no gaps.
- For children and infants or patients who need help using the Ventolin Mini Spacer, hold the mask firmly to the patient’s face.
Press down on the top of the Ventolin Inhaler canister to release one puff into the Ventolin Mini Spacer.

Breathe in and out slowly through the mouthpiece at least 4 times.

- Take the facemask away from your face and continue to breathe normally.
- If your doctor has told you to take two puffs, wait about 30 seconds before you take another puff by repeating the steps above.

**6. How to look after the Ventolin Mini Spacer**

With normal daily use, the Ventolin Mini Spacer should be replaced after 12 months.

The Ventolin Mini Spacer (and the facemask if this is being used) should be cleaned at least once a week as follows:

- Pull the mouthpiece section off the Ventolin Mini Spacer and slide out the extension as far as it will go.
- Wash the parts by hand in warm soapy water.
- Rinse all of the parts in clean water and shake off any excess water.
- Allow the parts to dry naturally in the air at room temperature. Don’t rub the inside of your Ventolin Mini Spacer with a cloth or polish as this may cause static electricity which can affect how the Ventolin Mini Spacer works.
- Don’t put the Ventolin Mini Spacer in a heated place to dry more quickly.

When the parts are completely dry, push the mouthpiece back onto the main section of the Ventolin Mini Spacer and close up the extension.

Store the Ventolin Mini Spacer in a clean and dry place.

**Clement Clark International Ltd.**
Edinburgh Way, Harlow, Essex CM20 2TT, UK

Imported by:
Hong Kong: GlaxoSmithKline Limited
23/F Tower 6, The Gateway 9 Canton Road, Tsim Sha Tsui, Hong Kong

Philippines: GlaxoSmithKline Philippines Inc.
2266 Chino Roces Avenue, Makati City 1231

VENTOLIN is a trade mark of the GSK group of companies.
© 2014 GSK group of companies. All rights reserved

Version number: GDS03
Date of issue: 30 October 2013

**IMPORTANT**

GSK Market is responsible for this product, its design and content. Ensure the artwork is thoroughly checked, all the text proof-read and approved. RSC GSX is responsible for site technical requirements and pre-press suitability.

GSK Market is responsible to advise RSC in case changes required impact the following:

- Formulation
- Tablet embossing
- Storage conditions
- Shelf Life
**Salbutamol**
**Ventolin®**
100mcg/ actuation Inhaler
Anti-asthma

**PRODUCT DESCRIPTION**
Each Salbutamol (Ventolin®) Inhaler is a pressurised metered-dose inhaler which delivers 100 micrograms salbutamol (as sulphate) per actuation, into the mouthpiece of a specially designed actuator. The inhaler also contains the CFC-free propellant HFA 134a. Each canister contains at least 200 actuations.

**PHARMACOLOGIC PROPERTIES**

**Pharmacodynamics**
Salbutamol is a selective beta2-adrenoceptor agonist. At therapeutic doses it acts on the beta2-adrenoceptors of bronchial muscle providing short acting (4 to 6 hour) bronchodilation with a fast onset (within 5 minutes) in reversible airways obstruction.

**Pharmacokinetics**

**Absorption**
After administration by the inhaled route, between 10 and 20% of the dose reaches the lower airways. The remainder is retained in the delivery system or is deposited in the oropharynx from where it is swallowed. The fraction deposited in the airways is absorbed into the pulmonary tissues and circulation but is not metabolised by the lung.

**Distribution**
Salbutamol is bound to plasma proteins to the extent of 10%.

**Metabolism**
On reaching the systemic circulation, salbutamol becomes accessible to hepatic metabolism and is excreted, primarily in the urine, as unchanged drug and as the phenolic sulphate. The swallowed portion of an inhaled dose is absorbed from the gastrointestinal tract and undergoes considerable first-pass metabolism to the phenolic sulphate. Both unchanged drug and conjugate are excreted primarily in the urine. The faeces are a minor route of excretion. The majority of a dose of salbutamol given intravenously, orally or by inhalation is excreted within 72 hours.

**Clinical Studies**

**Special Patient Populations**
**Children < 4 years of age**
Paediatric clinical studies conducted at the recommended dose (SB020001, SB030001, SB030002), in patients < 4 years with bronchospasm associated with reversible obstructive airways disease, show that the Inhaler has a safety profile comparable to that in children ≥ 4 years, adolescents and adults.

**Pre-clinical Safety Data**
In common with other potent selective beta-2 receptor agonists, salbutamol has been shown to be teratogenic in mice when given subcutaneously. In a reproductive study, 9.3% of foetuses were found to have cleft palate, at 2.5 mg/kg, four times the maximum human oral dose. In rats, treatment at the levels of 0.5, 2.32, 10.75 and 50 mg/kg/day orally throughout pregnancy resulted in no significant foetal abnormalities. The only toxic effect was an increase in neonatal mortality at the highest dose level as the result of lack of maternal care. A reproductive study in rabbits revealed cranial malformations in 37% of foetuses at 50 mg/kg/day, 78 times the maximum human oral dose.

**HFA 134a** has been shown to be non-toxic at very high vapour concentrations, far in excess of those likely to be experienced by patients, in a wide range of animal species exposed daily for periods of two years.

**INDICATIONS**
Salbutamol is a selective beta2 adrenoceptor agonist indicated for the treatment or prevention of bronchospasm. It provides short acting (4 hours) bronchodilation in reversible airways obstruction due to asthma, chronic bronchitis and emphysema. For patients with asthma salbutamol may be used to relieve symptoms when they occur and to prevent them prior to a known trigger. Bronchodilators should not be the only or main treatment in patients with persistent asthma. In patients with persistent asthma unresponsive to Salbutamol (Ventolin®), treatment with inhaled corticosteroids is recommended to achieve and maintain control. Failing to respond to treatment with Salbutamol (Ventolin®) may signal a need for urgent medical advice or treatment.

**DOSAGE AND ADMINISTRATION**
Salbutamol (Ventolin®) has a duration of action of 4 to 6 hours in most patients. Increasing use of beta2 agonists may be a sign of worsening asthma. Under these conditions a reassessment of the patient's therapy plan may be required and concomitant glucocorticosteroid therapy should be considered.

As there may be adverse effects associated with excessive dosing, the dosage or frequency of administration should only be increased on medical advice.
Salbutamol (Ventolin®) Inhaler is administered by the inhaled route only. In patients who find co-ordination of a pressurised metered-dose inhaler difficult a spacer may be used with Salbutamol (Ventolin®) Inhaler.

Babies and young children using the Salbutamol (Ventolin®) Inhaler may benefit from the use of a paediatric spacer device with a face mask (for example the BABYHALER®). (Recommended statement "for example the BABYHALER®" is for use only in those markets where the Babyhaler spacer device is available). (See Clinical Studies).

RELIEF OF ACUTE BRONCHOSPASM
- **Adults**
  - 100 or 200 micrograms.
- **Children**
  - 100 micrograms. The dose may be increased to 200 micrograms if required.

PREVENTION OF ALLERGEN OR EXERCISE-INDUCED BRONCHOSPASM
- **Adults**
  - 200 micrograms before challenge or exertion.
- **Children**
  - 100 micrograms before challenge or exertion. The dose may be increased to 200 micrograms if required.

CHRONIC THERAPY
- **Adults**
  - Up to 200 micrograms 4 times daily.
- **Children**
  - Up to 200 micrograms 4 times daily.

On demand use of Salbutamol (Ventolin®) should not exceed four times daily. Reliance on such supplementary use or a sudden increase in dose indicates deteriorating asthma (see Warnings and Precautions).

CONTRAINDICATIONS
Salbutamol (Ventolin®) is contraindicated in patients with a history of hypersensitivity to any of its components (see Excipients). Non-i.v. formulations of VENTOLIN must not be used to arrest uncomplicated premature labour or threatened abortion.

WARNINGS AND PRECAUTIONS
The management of asthma should normally follow a stepwise programme, and patient response should be monitored clinically and by lung function tests. Increasing use of short-acting bronchodilators, in particular beta-2 agonists to relieve symptoms indicates deterioration of asthma control. Under these conditions, the patient's therapy plan should be reassessed.

Sudden and progressive deterioration in asthma control is potentially life-threatening and consideration should be given to starting or increasing corticosteroid therapy. In patients considered at risk, daily peak flow monitoring may be instituted.

Salbutamol (Ventolin®) should be administered cautiously to patients with thyrotoxicosis.

Potentially serious hypokalaemia may result from beta-2 agonist therapy mainly from parenteral and nebulised administration.

Particular caution is advised in acute severe asthma as this effect may be potentiated by concomitant treatment with xanthine derivatives, steroids, diuretics and by hypoxia. It is recommended that serum potassium levels are monitored in such situations.

As with other inhalation therapy, paradoxical bronchospasm may occur, resulting in an immediate increase in wheezing after dosing. This should be treated immediately with an alternative presentation or a different fast-acting inhaled bronchodilator, if immediately available. Salbutamol (Ventolin®) Inhaler should be discontinued, and if necessary a different fast-acting bronchodilator instituted for ongoing use.

In the event of a previously effective dose of inhaled Salbutamol (Ventolin®) failing to give relief for at least three hours, the patient should be advised to seek medical advice in order that any necessary additional steps may be taken.

Patients’ inhaler technique should be checked to make sure that aerosol actuation is synchronised with inspiration of breath for optimum delivery of the drug to the lungs.

Effects on Ability to Drive and Use Machines
None reported.

DRUG INTERACTIONS
Salbutamol and non-selective beta-blocking drugs, such as propranolol, should not usually be prescribed together. Salbutamol (Ventolin®) is not contraindicated in patients under treatment with monoamine oxidase inhibitors (MAOIs).

PREGNANCY AND LACTATION

Fertility
There is no information on the effects of salbutamol on human fertility. There were no adverse effects on fertility in animals (see Pre-clinical Safety Data).

Pregnancy
Administration of drugs during pregnancy should only be considered if the expected benefit to the mother is greater than any possible risk to the foetus.

During worldwide marketing experience, rare cases of various congenital anomalies, including cleft palate and limb defects have been reported in the offspring of patients being treated with Salbutamol (Ventolin®). Some of the mothers were taking multiple medications during their pregnancies. As no consistent pattern of defects can be discerned, and baseline rate for congenital anomalies is 2 to 3%, a relationship with Salbutamol (Ventolin®) use cannot be established.
Lactation
As salbutamol is probably secreted in breast milk, its use in nursing mothers is not recommended unless the expected benefits outweigh any potential risk. It is not known whether salbutamol in breast milk has a harmful effect on the neonate.

ADVERSE EFFECTS
Adverse events are listed below by system organ class and frequency. Frequencies are defined as: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1000 to <1/100), rare (≥1/10,000 to <1/1000) and very rare (<1/10,000) including isolated reports. Very common and common events were generally determined from clinical trial data. Rare and very rare events were generally determined from spontaneous data.

Immune system disorders
Very rare: Hypersensitivity reactions including angioedema, urticaria, bronchospasm, hypotension and collapse

Metabolism and nutrition disorders
Rare: Hypokalaemia
Potentially serious hypokalaemia may result from beta2 agonist therapy

Nervous system disorders
Common: Tremor, headache
Very rare: Hyperactivity

Cardiac disorders
Common: Tachycardia
Uncommon: Palpitations
Very rare: Cardiac arrhythmias including atrial fibrillation, supraventricular tachycardia and extrasystoles

Vascular disorders
Rare: Peripheral vasodilatation

Respiratory, thoracic and mediastinal disorders
Very rare: Paradoxical bronchospasm

Gastrointestinal disorders
Uncommon: Mouth and throat irritation

Musculoskeletal and connective tissue disorders
Uncommon: Muscle cramps

OVERDOSAGE AND TREATMENT
The most common signs and symptoms of overdose with Salbutamol (Ventolin®) are transient beta agonist pharmacologically mediated events (see Warnings and Precautions and Adverse Reactions). Hypokalaemia may occur following overdosage with Salbutamol (Ventolin®). Serum potassium levels should be monitored. Lactic acidosis has been reported in association with high therapeutic doses as well as overdoses of short-acting beta-agonist therapy, therefore monitoring for elevated serum lactate and consequent metabolic acidosis (particularly if there is persistence or worsening of tachypnea despite resolution of other signs of bronchospasm such as wheezing) may be indicated in the setting of overdose.

SPECIAL PRECAUTIONS FOR STORAGE
Replace the mouthpiece cover firmly and snap it into position
Store below 30°C. Protect from frost and direct sunlight.
As with most inhaled medications in aerosol canisters, the therapeutic effect of this medication may decrease when the canister is cold.
The canister should not be broken, punctured or burnt, even when apparently empty.

INSTRUCTIONS FOR USE AND HANDLING
Testing your inhaler
Before using for the first time, remove the mouthpiece cover by gently squeezing the sides of the cover, shake the inhaler well, and release two puffs into the air to make sure that it works. If it has not been used for 5 days or more, shake it well and release 2 puffs into the air to make sure that it works.

Using your inhaler
1. Remove the mouthpiece cover by gently squeezing the sides of the cover.
2. Check inside and outside of the inhaler including the mouthpiece for the presence of loose objects.
3. Shake the inhaler well to ensure that any loose objects are removed and that the contents of the inhaler are evenly mixed.
4. Hold the inhaler upright between fingers and thumb with your thumb on the base, below the mouthpiece.
5. Breathe out as far as is comfortable and then place the mouthpiece in your mouth between your teeth and close your lips around it but do not bite it.
6. Just after starting to breathe in through your mouth press down on the top of the inhaler to release Salbutamol (Ventolin®) while still breathing in steadily and deeply.
7. While holding your breath, take the inhaler from your mouth and take your finger from the top of the inhaler.
Continue holding your breath for as long as is comfortable.
8. If you are to take further puffs keep the inhaler upright and wait about half a minute before repeating steps three to seven.
9. Replace the mouthpiece cover by firmly pushing and snapping the cap into position.

IMPORTANT
Do not rush Stages 5, 6 and 7. It is important that you start to breathe in as slowly as possible just before operating your Inhaler.
Practise in front of a mirror for the first few times. If you see 'mist' coming from the top of the inhaler or the sides of your mouth you should start again from stage two.
If your doctor has given you different instructions for using your inhaler, please follow them carefully. Tell your doctor if you have any difficulties.

CLEANING
Your inhaler should be cleaned at least once a week.
1. Remove the metal canister from the plastic casing of the inhaler and remove the mouthpiece cover.
2. Rinse the actuator thoroughly under warm running water.
3. Dry the actuator THOROUGHLY inside and out.
4. Replace the metal canister and mouthpiece cover.

DO NOT PUT THE METAL CANISTER INTO WATER.

AVAILABILITY
Salbutamol (Ventolin®) 100mcg/actuation Inhaler: 200 actuations per Metered Dose Inhaler

CAUTION
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.
Keep all medicines out of reach of children.

VENTOLIN and BABYHALER are registered trademarks of the GlaxoSmithKline group of companies.
©2009, GlaxoSmithKline. All rights reserved.

Imported by:
GlaxoSmithKline Philippines Inc
2266 Chino Roces Avenue, City of Makati
Tel. 892-0761

Manufactured by:
Glaxo Wellcome S.A.
Aranda de Duero, Spain
Repacked by:
GlaxoSmithKline Australia Pty. Ltd.
Boronia, Australia