AMIODARONE Hydrochloride

200 mg Scored Tablet

ANTHRYRRITIC

FORMULATION

Each tablet contains: Amiodarone Hydrochloride 200mg.

CLINICAL PARTICULARS

Indications

Prevention and treatment of:
- Life-threatening ventricular tachycardia that should be instituted in a hospital setting;
- Documented, symptomatic and intractable ventricular arrhythmia;
- Cardiac arrhythmia, where other forms of treatment have been established and in the event of resistance to or contraindication of other treatments;
- Treatment of supraventricular tachycardia causing slowing or reduction in atrial fibrillation or atrial flutter.

Amiodarone can be used in the presence of coronary artery disease and/or impaired left ventricular ejection fraction (LVEF).

Dosage and method of administration

Initial treatment

The usual dosage regimen is 3 tablets per day, for 8 to 10 days. In some cases, the initial treatment has involved higher doses (4 to 5 tablets per day), always for short periods and under intensive monitoring.

Maintenance treatment

Swing the minimum effective dose, which varies depending on the patient, ranging from 1 tablet per day (1 tablet every 2 days) to 2 tablets every day.

Contraindications

The use of the product is contraindicated in the following cases:
- Hypersensitivity reactions.
- Heart failure.
- Pre-existing thyroid abnormalities.
- Presence of serious arrhythmias.
- Pregnancy, unless exceptional circumstances (see Pregnancy).
- Concurrent diuretic use.
- Combination with medicinal products liable to induce Torsades de Pointes.

Hyperthyroidism may occur during amiodarone treatment, or up to several months after discontinuation of therapy. Clinical findings may include: tachycardia, anxiety, nervousness, sweating, insomnia, weight loss, tremor, and peripheral edema. In the case of severe cases, with clinical presentation of thyrotoxicosis, and sometimes fatal require emergency therapy and hospitalization. Thyroid function tests (TSH, T4, T3, T3u) should be obtained every 1 to 2 months.

In combination with medicinal products liable to induce Torsades de Pointes, if this combination cannot be avoided, prior to the QT interval and ECG monitoring is strongly recommended.

Some phenothiazine neuroleptics (chlorpromazine, cyamemazine, levomepromazine, thioridazine, thiothixene, haloperidol, chlorpromazine, haloperidol, and chlorpromazine) may increase the risk of ventricular arrhythmias, particularly Torsades de Pointes.

Side effects of this combination with other medicinal products that may increase the risk of ventricular arrhythmias should be monitored closely.

Other effects are related to the treatment discontinuation. If discontinuation of treatment is necessary, a gradual tapering should be performed, starting with 1 to 2 tablets every 2 days, then 1 tablet every 3 days, and finally 1 tablet every 4 days.

For patients previously treated with amiodarone, it is therefore recommended that these patients be closely monitored during arterial ventilation (see Adverse Reactions). Interactions

Pharmacodynamic Interactions

- Drugs inducing Torsades de Pointes or prolonging QT
  - Antiarrhythmic drugs that may induce Torsades de Pointes is contraindicated (see Contraindications).
  - Class IA antihyrritnics (quinidine, hydroxyquinidine, disopyramide).
  - Class III antihyrritnics (diltiazem, lidocaine, tocainide).
  - Other medicinal products, such as bepridil, clofibrate, diphenylhydantoin, amiodarone, cyclosporine, mexiletine, procainamide, propafenone (see Interactions).

- Beta-blockers (see Interactions).

- Drugs lowering heart rate or causing automaticity or conduction disorders
  - Class IA and Class III antihyrritnics (diltiazem, tocainide).
  - Beta-blockers (other than solod form [combined combination] and esmolol (combination requiring precautions, see Interactions).)

- Contrast agents, automaticity and conduction disorders (suppressed compensatory sympathetic mechanisms).
  - Other medicinal products with a risk of cardiac bradyarrhythmias.
  - Beta-blockers in heart failure (bisoprolol, carvedilol, metoprolol).

- Esmolol (combination requiring precautions, see Interactions).

- Intravenous diltiazem

- Solod form and intravenous administration, this combination should not be avoided, slow continuous clinical and ECG monitoring is strongly recommended.

- Oral diltiazem

- Combination with other medicinal products which may increase the risk of Torsades de Pointes, other types of toxicities should be used.

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metabolism by amiodarone. Clinical and ECG monitoring and, if necessary, control of hepatic enzymes and signs of liver disease. The development of idiosyncratic and liver damage.

Orally

- Close monitoring of plasma concentrations of amiodarone and its active metabolites. CYP450 inhibitors may have a potential to inhibit amiodarone metabolism and to increase its exposure. It is recommended to avoid amiodarone in breast milk in significant quantities and is therefore contraindicated in breastfeeding.

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