Isosorbide Dinitrate
Isoket®
1mg/mL Solution for Intravenous Infusion

PRODUCT DESCRIPTION
Each mL of Isosorbide Dinitrate (Isoket®) solution for intravenous infusion contains 1mg of isosorbide dinitrate.

INDICATIONS
For acute myocardial infarction with left heart failure; acute ventricular failure of any etiology; severe unstable angina-pectoris

DOSEAGE AND ADMINISTRATION
The dosage is to be adjusted to the patient’s need and the response of the clinical and haemodynamic variables to be monitored. In clinical practice, treatment is started with a dose of 1-2mg / hr then the dose is adjusted to the individual requirements; maximum doses normally are of 8-10mg / hr. Isosorbide Dinitrate (Isoket®) solution should be administered in diluted form by continuous intravenous infusion by means of automatic infusion devices in a hospital setting under constant cardiovascular monitoring.

Depending on the kind and the severity of the disease, the usual follow-ups (symptoms, blood pressure, heart rate, elimination of urine) should be completed by invasive haemodynamic measurement. Isosorbide Dinitrate (Isoket®) solution is compatible with all infusion solutions usually administered in hospital such as physiological saline 5-30% glucose solution, Ringer’s solution containing protein. Materials made of polyethylene (PE) suitable for infusing Isosorbide Dinitrate (Isoket®) solution. Infusion material made of polyvinyl chloride (PVC) or polyurethane (FU) has been shown to induce a loss of the active ingredient due to absorption which has to be substituted by an increased dose. The solution concentrate is sterile but not preserved. Isosorbide Dinitrate (Isoket®) solution should be admixed under a septic condition immediately after opening.

DOSAGE CHART FOR DILUTED SOLUTIONS

<table>
<thead>
<tr>
<th>0.1mg Isosorbide Dinitrate / mL (0.01%)</th>
<th>0.2mg Isosorbide Dinitrate / mL (0.02%)</th>
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</thead>
<tbody>
<tr>
<td>µdrops / min</td>
<td>mg / hour</td>
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<tr>
<td>mL / hour</td>
<td>Drops / min</td>
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<tr>
<td>10</td>
<td>3-4</td>
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<td>20</td>
<td>7</td>
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<td>90</td>
<td>30</td>
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<td>100</td>
<td>33</td>
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</tbody>
</table>

1mL= 60 paediatric microdrops = 20 standard drops

CONTRAINDICATIONS
- Acute circulatory failure (shock circulatory collapse)
- Marked hypotension (systolic blood pressure < 95 mmHg)
- Cardiogenic shock, unless a sufficiently high left ventricular and diastolic pressure is warranted by intra-aortic counterpulsation of positive isotropic drugs

WARNINGS AND PRECAUTIONS
In acute myocardial infarction with low filling pressures Isosorbide Dinitrate (Isoket®) should only be used with caution. The administration of Isosorbide Dinitrate (Isoket®) solution in acute myocardial infarction should be done under medical supervision in order to avoid a blood pressure fill below 95 mmHg systolic. Animal experiments have not revealed any evidence of Isosorbide Dinitrate-induced embryonal damage. Nevertheless, Isosorbide Dinitrate (Isoket®) solution should be given to pregnant or breast-feeding women only under medical observation.

DRUG INTERACTIONS
Concurrent intake of hypertensive agents, calcium channel blockers, vasodilators, tricyclic antidepressants or alcohol may potentiate the hypotensive effect of Isosorbide Dinitrate (Isoket®) solution. If dihydroergotamine is concomitantly administered, Isosorbide Dinitrate (Isoket®) solution may induce an increase of the dihydroergotamine effect.

ADVERSE EFFECTS
Particularly at the start of treatment vasodilation-related headache may occur frequently. Flush, dizziness, orthostatic hypotension and reflex tachycardia have been documented in some instances. Rarely, collapse syndromes may develop, sometimes accompanied by bradycardiac rhythm disturbances. In rare instances when blood pressure drops markedly, angina pectoris symptoms may be intensified.

STORAGE CONDITIONS
Store at temperatures not exceeding 25°C.
AVAILABILITY
Isosorbide Dinitrate (Isoket®) solution for intravenous infusion: 10mL ampoules (Box of 10’s)

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

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