DOPACARD® 50 mg/5 ml
Concentration for Solution for Infusion
Dopexamine hydrochloride

1. What DOPACARD is and what it is used for

The name of this medicine is DOPACARD 50 mg/5 ml Concentrate for Solution for Infusion. The active ingredient in this medicine is dopexamine hydrochloride which belongs to a group of medicines called sympathomimetics.

DOPACARD is used to widen your blood vessels and allow your heart to pump blood easily to your vital organs. It can also be used as a support treatment during times when your heart is not pumping blood around your body properly.

2. Before you use DOPACARD

• Have an allergy (hypersensitive) to dopexamine hydrochloride or any of the other ingredients (dopexamine hydrochloride).
• Are on, or have recently taken, medicines for depression called monoamine oxidase inhibitors (MAOI).
• Have had a reaction to an adrenaline injection.
• Have had phaeochromocytoma.
• Have a stomach condition called pylorostenosis.
• Have a stomach condition called parietal cell hypertrophy.
• Have had a reaction to a medicine containing dopamine.
• Have any condition which can affect your blood sugar level e.g. diabetes.
• Have ever had a heart attack.
• Have been told by your doctor you have poor blood circulation.
• Have an adrenal gland disorder.
• Have an aortic stenosis.
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3. How to use DOPACARD

• Take with food or milk.
• Drink plenty of water.
• Take exactly as directed by your doctor.
• Allow a 1 mg/ml concentration of DOPACARD to be diluted with sterile water for injection.

4. What you need to know before you use DOPACARD

• If you are pregnant or planning to become pregnant.
• If you are breast-feeding.
• If you have any other conditions.

5. How to store DOPACARD

• Keep in the refrigerator. Do not freeze.
• Keep tight and protected from light.
• Do not use after the expiry date.

6. Further information

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2. BEFORE YOU ARE GIVEN DOPACARD

You should not be given DOPACARD if you:

• Have a condition which can affect your blood sugar level e.g. diabetes.
• Have kidney problems (for example, a partially blocked artery).
• Have any bleeding problems (for example, a partially blocked artery).
• Have any condition which can affect your blood sugar level e.g. diabetes.

DOPACARD must be diluted before use. For instructions on dilution of the product before use, see the special precautions for disposal and handling section.

7. Possible side effects

• No studies on the effects on the ability to drive and use machines have been performed.

8. medicines for depression called monoamine oxidase inhibitors (MAOI).
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• Have an adrenal gland disorder.
• Have an aortic stenosis.
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DOPACARD® 50 mg/5 ml
Concentration for Solution for Infusion
(Dopexamine hydrochloride as a 1% solution w/v)

PHARMA LEAFLET: INFORMATION FOR THE USER

General

Side effects are shown in the tables below. Adverse reactions are listed below as MedDRA preferred term by system organ class and frequency (frequencies are defined as: very common ≥ 1/10; common ≥ 1/100 to < 1/10; rare ≥ 1/10000 to < 1/1000; very rare 2 cases in 10000; isolated: only once in 10000).

10. What to do if you think you may be pregnant

If you are pregnant, tell your doctor before taking any medicine. It is especially important if you are taking any of the following:

• Blood tablets (vitamin B12 and folic acid).
• Medicines for heart conditions e.g. digoxin.
• Blood-lowering tablets e.g. diuretics.
• Medicines for high blood pressure e.g. propranolol.
• Hormone replacement or oestrogen therapy.

11. What to do if you are breast-feeding

DOPACARD is not recommended for use during pregnancy and breast-feeding. If you are pregnant, your doctor may prescribe you to be given DOPACARD.
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Hospira S.p.A., Via Fosse Ardeatine 2, 20060 Liscate (MI), Italy.

UK
West Yorkshire,
Castleford,
Whistler Drive,
Marketing Authorisation Holder

DOPACARD comes in boxes of 10 clear glass ampoules each containing 5 ml 1% w/w solution of dopexamine hydrochloride as the active substance. It also contains:

- Filler: 0.9% w/w sodium chloride
- Preservative: 0.01% w/w benzyl alcohol

Common side effects occurring in less than 1 in 10, but in more than 1 in 100 patients treated:

- Racing or irregular heart beat, unusual heart beat
- High or low blood pressure
- Abnormal heart trace (ECG), warning of heart failure, heart attack, chest pain (angina)
- Vomiting (being sick)
- Shortness of breath
- Increased sweating
- Headaches
- Shaking
- Kidney failure
- Soreness of muscles
- Fluid on the lungs
- Blood pressure
- Blushing

Rarely, mildness and occur in the child who enters the vein.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard

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There is no significant loss of potency associated with this change.

<table>
<thead>
<tr>
<th>Solution (ml)</th>
<th>Extracted (ml)</th>
<th>ampoules to be added</th>
<th>µg/ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>5</td>
<td>1</td>
<td>500</td>
</tr>
<tr>
<td>250</td>
<td>10</td>
<td>2</td>
<td>400</td>
</tr>
<tr>
<td>250</td>
<td>20</td>
<td>4</td>
<td>800</td>
</tr>
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</table>

Pre-clinical Safety Data

The half-life of DOPACARD is blood is short (see Pharmacokinetic Properties). Consequently, the effects of overdosage are likely to be short-lived provided that administration is discontinued promptly. Overdosage caused by deliberate or accidental overdosage can produce effects on the cardiovascular system similar to those produced by excessive doses of dopamine. Effects of overdosage are likely to be related to pharmacological actions and include tachycardia, hypotension, arrhythmias, convulsions, seizures, nausea and vomiting, headache, sweating, shortness of breath and peripheral pooling. Management should be symptomatic and supportive. These factors are associated with symptoms in overdose and blood pressure return to normal. In asystole patients avoid heart rate and blood pressure return to normal. In asystole patients avoid heart rate and blood pressure return to normal.

DOPACARD should only be diluted with 0.9% Sodium Chloride Injection, 5% Dextrose Injection, Hartmann’s Solution (Compound Sodium Lactate Intravenous Infusion) or Dextrose 4%/Saline 0.18% Injection.

The appropriate volume of site solution should be aspirated from the solution bag, or by the tubing set in the administration, if any, used to carry the medication to the patient, and the site cleared of all other solutions or medications. The diluent should be transferred and used in the manner specified for DOPACARD.

Incompatibilities

DOPACARD should not be mixed with any other medicinal products before administration except those mentioned in Special precautions for disposal and other handling.

Procedure

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