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

Doctor information
Trade Name of the Medicinal Product
DOPACARD® 50mg/5ml Concentrate for Solution for Infusion.

Qualitative and Quantitative Composition
Dopexamine hydrochloride is a 1% solution (w/v). Each 5ml ampoule contains:

Pharmaceutical form
Concentrate for injection for infusion.

Clinical particulars
Therapeutic indications
DOPACARD is indicated for short-term intravenous administration to patients in acute hypotension, through peripheral vasodilatation, renal and mesenteric vasodilatation, combined with a mild positive inotropic effect required for the treatment of exacerbations of chronic heart failure, or heart failure associated with cardiac surgery.

Posing and method of administration
For intravenous use only.

DOPACARD must be injected before use.

Adverse effects
Adults and the elderly
Dopexamine has an active plasma half-life of approximately 1 hour. The duration of therapy is dependent upon the patient’s overall response to treatment. Contraindications
- Known hypersensitivity to dopexamine hydrochloride or to dopamine (dilution vehicle).
- Patients who are receiving monoamine oxidase inhibitors (MAO-I).
- Thromboembolic events.

Patients with left ventricular outflow obstruction such as hypertrophic obstructive cardiomyopathies or aortic stenosis. In such patients, positive inotropic activity may increase left ventricular outflow obstruction and sudden vasodilatation may cause hypotension.

Special warnings and precautions for use
- Contraindication of hypoglycaemia must be achieved prior to administration of DOPACARD.
- DOPACARD must be diluted and be commuted during infusion as vasodilatation occurs due to treatment.
- The drug should be administered by a person with adequate skill and knowledge of fluid and blood volume control during administration of DOPACARD.

DOPACARD should not be administered to patients with severe hypotension or markedly reduced systemic vascular resistance with specific resuscitation measures having been taken to restore blood pressure to a clinically acceptable level.

Special warnings and precautions for use
- Correction of hypoglycaemia must be achieved prior to administration of DOPACARD.
- DOPACARD should not be administered to patients with severe hypotension or markedly reduced systemic vascular resistance with specific resuscitation measures having been taken to restore blood pressure to a clinically acceptable level.

In patients with a marked reduction in systemic vascular resistance, DOPACARD should not be administered to patients with severe hypotension or markedly reduced systemic vascular resistance with specific resuscitation measures having been taken to restore blood pressure to a clinically acceptable level.

DOPACARD may cause in patients with a clinical history of chronic heart failure especially following acute myocardial infarction or recent episodes of angina pectoris, as a tachycardia may increase myocardial oxygen demand and further exacerbate myocardial ischaemia.

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2. BEFORE YOU ARE GIVEN DOPACARD

You should not be given DOPACARD if you:
- Are allergic (anaphylactic or anaphylactoid) to dopexamine or any other component of DOPACARD.
- Are pregnant or breast-feeding.

DOPACARD is not suitable for use in children.

Take special care with DOPACARD if you:
- Have been told by your doctor you have poor blood circulation.
- Have ever had a chest pain (angina).
- Have heart failure or have had a heart attack.
- Have been told by your doctor you have poor blood circulation.
- Have been told by your doctor you have a history of chest pain.

If any of the above apply to you, you should speak to your doctor before taking this medicine.

Taking other medicines
- Take DOPACARD carefully if you are taking or have recently taken other medicines, including medicines obtained without a prescription. This is especially important if you are taking any of the following:
  - Blood thinning medicines (e.g. warfarin, aspirin, clopidogrel). DOPACARD can interfere with the activity of these medicines and may increase the risk of major bleeding.
  - Medicines for high blood pressure (e.g. beta-blockers, calcium channel blockers).
  - Medicines for nausea and sickness (e.g. prochlorperazine).
  - Medicines for heart failure.

In this situation:
- If you have any concerns, consult your doctor.
- This medicine has been prescribed for you. Do not share it with others. It may harm them, even if their symptoms are the same as yours.
Pregnancy and breast-feeding

DOPACARD is not recommended for use during pregnancy and breast-feeding. If you are pregnant, think you might be pregnant, or are breast-feeding tell your doctor or pharmacist before taking DOPACARD.

3. HOW DOPACARD WILL BE GIVEN

Your doctor will ensure you have sufficient fluid circulating in your body before giving DOPACARD.

The doctor or other health care professional will make up the correct dose of DOPACARD. The dose will be given to you by a slow injection or by a drip over a period of time (infusion), for a maximum of 48 hours. Your doctor will ensure your response to DOPACARD.

If you have too much DOPACARD:

It is unlikely that you will be given too much DOPACARD, but if this happens your doctor will treat any symptoms that may occur.

4. POSSIBLE SIDE EFFECTS

Like all medicines, DOPACARD can cause side effects, although not everybody gets them. The following side effects have been reported:

• Racing or irregular pulse
• Fast and shallow breathing
• Sweating
• Nausea and vomiting
• Dizziness and fainting
• Seizures, loss of consciousness
• Bleeding

If you experience any side effects while receiving DOPACARD tell your doctor or health care professional immediately.

5. HOW TO STORE DOPACARD

Keep all medicines out of the reach and sight of children.

Keep the ampoule in the outer carton.

DOPACARD must not be used after the expiry date printed on the ampoule.

6. FURTHER INFORMATION

What DOPACARD contains

DOPACARD contains 5 ml of 1% dopexamine hydrochloride as the active substance. It also contains disodium edetate, hydrochloric acid and water for injections as the inactive ingredients.

What DOPACARD looks like and contents of the pack

DOPACARD comes in boxes of 10 clear glass ampoules each containing 5 ml 1% w/w solution of dopexamine hydrochloride.

Marketing Authorisation Holder

Cephalon UK Limited 1 Albany Place, Hyde Way, Welwyn Garden City, Hertfordshire, AL7 3BT, UK.

Manufacturer

Hospira S.p.A., Via Fosse Ardeatine 2, 20060 Liscate (MI), Italy.

This leaflet was last approved in March 2010

For more information please call 0800 763 4660 or e-mail: UKMedInfo@cephalon.com

29/03/10

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