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Neoatricon 1.5 mg/mL solution for infusion
dopamine hydrochloride

UK/LF/066 V01

PLF190

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Package leaflet: Information for the user

Read all of this leaflet carefully before your child starts using this medicine because it contains important information for your child.

– Keep this leaflet. You may need to read it again.
– If you have any further questions, ask your doctor or nurse.
– If you are concerned about any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Neoatricon is and what it is used for
2. What you need to know before your child uses Neoatricon
3. How to use Neoatricon
4. Possible side effects
5. How to store Neoatricon
6. Contents of the pack and other information

1. What Neoatricon is and what it is used for

Neoatricon contains the active substance dopamine hydrochloride. Dopamine is a substance that occurs naturally in the body. It increases blood pressure by activating specific receptors (targets), which causes narrowing of the blood vessels.

It may be used to help the heart and circulation work more effectively under special circumstances in sick babies (including those born prematurely) and children and adolescents below 18 years of age.

2. What you need to know before your child uses Neoatricon

Your child should not be given Neoatricon

- If your child is allergic to dopamine hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- If your child has phaeochromocytoma (a tumour of the adrenal gland).
- If your child has an uncorrected atrial or ventricular tachyarrhythmia (abnormal or irregular heartbeats in the upper or lower chambers of the heart) or ventricular fibrillation (dangerous, irregular and uncoordinated contractions of the lower chambers of the heart)
- If your child has an overactive thyroid gland.
- If your child is receiving cyclopropane or halogenated hydrocarbon anaesthetics.

Talk to your doctor if you are not sure if any of the above apply to your child.

Warnings and precautions

Talk to your doctor or nurse before using Neoatricon if:

- your child has any heart-related problems
- your child uses or has recently used monoamine oxidase inhibitors (MAOIs), which are for example used to treat depression; (see section 'Other medicines and Neoatricon').
- your child is suffering or has suffered from peripheral vascular disease (problems related to blood circulation in their hands and feet)
- your child has any kidney or liver diseases
- your child has low blood volume. Your child's doctor will take steps to get their blood volume up to normal before giving them dopamine hydrochloride
- your child has sepsis (a serious bacterial infection)
- your child has diseases associated with an increased pressure in the arteries of the lungs
- your child suffers from a certain form of glaucoma (narrow-angle glaucoma)

While receiving Neoatricon, your child's condition will be closely monitored by the attending medical staff and the dose of Neoatricon adjusted as necessary.

Neoatricon may increase the risk of infection, so your doctor will closely monitor your child and infection prevention measures will be put in place.

Your doctor will reduce the use of Neoatricon gradually to avoid low blood pressure.

Dopamine hydrochloride may lead to changes in your child's blood test. Your doctor may take blood samples to monitor for these.

Other medicines and Neoatricon

Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines, including those obtained without prescription.

Special care is needed if your child is using other medicines as some could interact with Neoatricon, for example:

- anaesthetics.
- certain medicines used to treat diabetes (e.g. repaglinide, sulfonylureas etc.) Dopamine hydrochloride may increase blood glucose levels may interfere with antidiabetic medicines.
- certain medicines used to treat depression (tricyclic antidepressants), such as amitriptyline , desipramine, doxepin, imipramine, nortriptyline.
- Monoamine-oxidase inhibitors (MAOI), a type of medicine used to treat depression, such as selegiline, isocarboxazid, phenelzine, tranylcypromine, rasagiline, linezolid.
- phenytoin, a medicine used to treat epilepsy.
- alpha- and beta-blockers (medicines which are often used for treating blood pressure and heart disorders), such as doxazosin, prazosin, terazosin, acebutolol, atenolol, bisoprolol, metoprolol, nadolol, nebivolol, propranolol.
- ergotamine, a medicine used to treat headaches.
- metoclopramide a medicine used to treat feeling sick (nausea) and being sick (vomiting)
- guanethidine, a medicine used to treat high blood pressure.
- diuretics (medicines that increase urine production), such as bumetanide, torsemide, and furosemide.

If your child is taking any of the medicines listed above please ask your doctor for further information about the possible consequences of these interactions.

Pregnancy and breast-feeding

Neoatricon is intended for use in children. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine.

If you are a woman of child-bearing age, you should practise effective contraception during treatment with Neoatricon. Neoatricon is not recommended during pregnancy.

However, your doctor will only use this medicine if the expected benefits outweigh any potential risk to your baby.

It is unknown whether dopamine is excreted in breast milk. A risk to the suckling child cannot be excluded.

Driving and using machines

Not applicable as this product is given in a hospital setting.

Neoatricon contains sodium metabisulfite

This excipient may rarely cause severe hypersensitivity (severe allergy) reactions and bronchospasm (excessive and prolonged contraction of the airway muscles causing breathing difficulty).

This medicinal product contains less than 23 mg of sodium in each dose and therefore is essentially 'sodium-free'.

3. How to use Neoatricon

Dose and method of administration

Your doctor will decide on the most suitable dose for your child. The dose will depend on your child's medical condition and body weight. The rate of administration will be carefully controlled and adjusted according to your child's response.

This medicine will be given by infusion (drip) in a large vein under the supervision of a doctor. In newborns, the medicine may also be given into the umbilical cord.

Your child's breathing, blood pressure, oxygen levels, kidney function and other vital signs will be watched closely while they are receiving Neoatricon.

If your child's blood volume is low, your child may be given a transfusion of blood or a plasma expander (fluids that increase the volume of circulating blood) before this medicine is given.

Tell your doctor or nurse if your child feels any burning, pain or swelling around the intravenous needle when dopamine hydrochloride is given. If the medicine infusion escapes from the vein into the surrounding tissues, it may damage (e.g. blister; tissue death) the surrounding tissues. Tell your doctor if you or your child notice any pain or swelling at the injection site so that the appropriate treatment may be given.

If you are given too much or too little dopamine hydrochloride

This medicine will be given to your child in a hospital, under the supervision of a doctor. It is unlikely that your child will be given too much or too little. However, tell your doctor or nurse if you have any concerns.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious adverse reactions

If you notice any changes in the way your child feels during or after the treatment, tell your doctor immediately:

- severe allergic reaction – your child may experience a sudden itchy rash (hives), swelling of the hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in swallowing or breathing), and your child may feel they are going to faint (frequency unknown)
- gangrene (decay and death of tissue; you may notice a change in skin colour even to black) (frequency uncommon).
- severe palpitations (frequency unknown); ventricular tachycardia up to ventricular fibrillation (uncommon).

These are serious side effects. Your child may need urgent medical attention.

Other adverse reactions

If any of the following happens, tell your doctor as soon as possible:

Common side effects (may affect up to 1 in 10 people)
- sinus tachycardia (rapid heartbeat)
- palpitation (a forceful heartbeat that may be rapid or irregular)
- anginal pain (a type of chest pain caused by reduced blood flow to the heart)
- ectopic heartbeat (change in a heartbeat that is otherwise normal)
- dyspnoea (shortness of breath)
- hypotension (low blood pressure)
- vasoconstriction (narrowing of blood vessels)
- nausea (feeling sick)
- vomiting
- headache

Uncommon side effects (may affect up to 1 in 100 people)
- hypertension (high blood pressure)
- abnormalities in the electrocardiogram (a tracing of electrical currents in the heart – aberrant conduction)
- mydriasis (dilation of the pupil of the eye)
- bradycardia (slow heart rate)
- azotaemia (abnormally high levels of nitrogen-containing compounds, such as urea, in the blood)
- episodes of abnormally fast heart rate (supraventricular tachycardia and ventricular tachycardia)
- very fast contractions of the lower heart chambers, rendering the heart unable to pump blood effectively (ventricular fibrillation)
- piloerection (goose bumps)
- gangrene (decay and death of tissue; you may notice a change in skin colour even to black)
- skin necrosis (death of tissue)

Not known (cannot be estimated from the available data)
- increased risk of bleeding after operations in the abdominal (belly) region or in patients with a tendency to bleed in the gastrointestinal tract (stomach and gut)
- an increase in hypoxaemia (a low level of oxygen in the blood) in ventilator-dependent patients
- decrease in renal (kidney) blood flow at higher doses, due to narrowing of blood vessels
- infection
- suppression of pituitary function
- local necrosis due to extravasation (infusion escapes from the vein and damages surrounding tissue)

Reporting of side effects

If your child gets any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via internet at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Neoatricon

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the vial and carton after 'EXP'. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions. Keep the container in the outer carton in order to protect from light.

Neoatricon is a single use vial only. After first opening the medicine should be used immediately. Unused portions should be discarded.

Do not use this medicine if you notice an opaque, cloudy or discoloured solution.

6. Contents of the pack and other information

What Neoatricon contains

The active substance is dopamine hydrochloride.

Neoatricon 1.5 mg/mL solution for infusion

Each millilitre of solution contains 1.5 milligrams of dopamine hydrochloride. Each vial contains 45 mg of dopamine hydrochloride in 30 mL.

The other excipients are sodium metabisulfite (E223) (see section 2 "Neoatricon contains sodium metabisulfite"), water for injections, sodium hydroxide (for pH adjustment) and dilute hydrochloric acid (for pH adjustment).

What Neoatricon looks like and contents of the pack

Neoatricon solution for infusion is a clear, colourless or pale-yellow solution. It comes in clear glass vial with a rubber stopper and is sealed with an aluminium flip-off seal.

Pack size

Neoatricon 1.5 mg/mL is presented as one 30 mL vial, packed in an outer carton.

Marketing Authorisation Holder
BrePco Biopharma Limited,
Suite One, The Avenue, Beacon Court,
Sandyford,
Dublin D18 HX31,
Ireland

Manufacturer
Pharmadox Healthcare Ltd.,
KW20A Kordin Industrial, Park,
Paola PLA3000,
Malta

For any information about this medicine, please contact the local representative of the marketing authorisation holder:

United Kingdom (Northern Ireland)
Piramal Critical Care Limited,
Suite 4 , Heathrow Boulevard, 280 Bath Road, West Drayton,
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http://www.piramalcriticalcare.com/uk/

This leaflet was last revised in 12/2024.

The following information is intended for healthcare professionals only:

Infusion of dopamine hydrochloride solution should begin at a rate of 5 µg/kg/min and increase gradually in 5 µg/kg/min increments. The recommended dose range is 5 – 10 µg/kg/min. Doses above 10 µg/kg/min up to a maximum of 20 µg/kg/min may be administered if considered justified.

This medicinal product is hypotonic.

Instructions for use and handling

Inspect the medicinal product before use.

For intravenous use. Administer via a central line [Umbilical venous catheter (UVC), Longline, or Surgical central venous line (CVL)]. If no central access is available, use a cannula in large vein.

A suitable metering device is required in the infusion system to control the rate and flow.

Maintaining aseptic technique during the transfer of medication from a vial to a suitable metering device is essential to prevent contamination and ensure patient safety. This involves proper hand hygiene, using sterile equipment, and following meticulous procedures to avoid introducing microorganisms.

For single use.

Discard any unused contents.

Do not dilute.

Do not use if the solution is discoloured.

The maximum acceptable duration for one single vial administration is 24-hours.

Incompatibilities

Neoatricon solution for infusion should not be added to any alkaline intravenous solutions, i.e. sodium bicarbonate. In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

It is suggested that admixtures containing gentamicin sulphate, cephalothin sodium, cephalothin sodium neutral or oxacillin sodium should be avoided unless all other viable alternatives have been exhausted.

Admixtures of ampicillin and dopamine in 5% glucose solution are alkaline and incompatible and result in decomposition of both drugs. They should not be admixed.

Admixtures of dopamine, amphotericin B in 5% glucose solution are incompatible as a precipitate forms immediately on mixing.

In use storage precautions

This medicinal product does not require any special temperature storage conditions.

Keep the container in the outer carton in order to protect from light.