EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Neoatricon (*dopamine hydrochloride*)

An overview of Neoatricon and why it is authorised in the EU

What is Neoatricon and what is it used for?

Neoatricon is used to treat hypotension (low blood pressure) in newborn babies, infants and children less than 18 years of age who have unstable blood pressure.

Neoatricon contains the active substance dopamine hydrochloride and is a hybrid medicine. This means that it is similar to a reference medicine containing the same active substance, but there are certain differences between the two.

Unlike the reference medicine (Sterile Dopamine Concentrate BP 40mg/mL, Ireland), Neoatricon is used in children and its strength and what it is used for are different from those of the reference medicine.

How is Neoatricon used?

Neoatricon is given as an infusion (drip into a vein) in a large vein under the supervision of a doctor. In newborns, the medicine may also be given into the umbilical cord. The amount of Neoatricon the patient receives depends on how they respond to treatment.

The medicine can only be obtained with a prescription. For more information about using Neoatricon, see the package leaflet or contact your healthcare provider.

How does Neoatricon work?

Neoatricon contains the active substance dopamine hydrochloride. It works mainly by attaching to specific receptors (targets) called adrenergic receptors. Attaching to these receptors causes blood vessels to become more narrow and the heart to beat harder, thereby increasing blood pressure.

What benefits of Neoatricon have been shown in studies?

The main benefits of dopamine have been shown in published studies. The studies showed that dopamine leads to an increase in arterial blood pressure, which helps to improve the blood supply to the organs of newborns, infants and children who have severe problems with their blood circulation.

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What are the risks associated with Neoatricon?

For the full list of side effects and restrictions with Neoatricon, see the package leaflet.

The most common side effects with Neoatricon (which may affect up to 1 in 10 people) include headache, problems with heart rhythm and electrical conduction in the heart, high blood pressure, piloerection (goosebumps), azotaemia (increased levels of nitrogen and other waste products in the blood), skin necrosis (death of skin tissue) and gangrene (decay and death of tissue)

Why is Neoatricon authorised in the EU?

There is evidence from the published literature about the use of dopamine to increase blood pressure in children whose blood pressure is unstable. Important side effects include problems with the heart rhythm and reduced blood flow to tissues. The European Medicines Agency concluded that Neoatricon's benefits are greater than its risks and that it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Neoatricon?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Neoatricon have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Neoatricon are continuously monitored. Suspected side effects reported with Neoatricon are carefully evaluated and any necessary action taken to protect patients.

Other information about Neoatricon

Neoatricon received a marketing authorisation valid throughout the EU on 27 May 2024.

Further information on Neoatricon can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/neoatricon

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