EMA/CHMP/61250/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Neoatricon

dopamine hydrochloride

On 21 March 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a paediatric use marketing authorisation (PUMA) for the medicinal product Neoatricon, intended for treatment of hypotension in neonates, infants and children under 18 years of age. The applicant for this medicinal product is BrePco Biopharma Limited.

Neoatricon will be available as a 1.5 mg/mL and 4.5 mg/mL solution for infusion. The active substance of Neoatricon is dopamine hydrochloride, belonging to a therapeutic class of adrenergic and dopaminergic agents (ATC code: C01CA04). By stimulating adrenergic receptors of the sympathetic nervous system, dopamine hydrochloride increases the systemic vascular resistance and blood pressure in a dose-dependent manner.

The benefit of Neoatricon in the treatment of hypotension in neonates, infants and children <18 years old was demonstrated by published medical literature.

The most common side effects are headache, ectopic heart beats, tachycardia, anginal pain, palpitation, hypotension, vasoconstriction, dyspnoea, nausea and vomiting.

Neoatricon is a hybrid medicine[2] of Sterile Dopamine Concentrate BP 40mg/mL, which has been authorised in the EU since 17 August 1989. Neoatricon contains the same active substance as Sterile Dopamine Concentrate BP 40mg/mL but is available in lower concentrations (1.5 mg/mL and 4.5 mg/mL).

Studies have demonstrated the satisfactory quality of Neoatricon. Since Neoatricon is administered intravenously and is 100% bioavailable, a bioequivalence study versus the reference product was not required.

The full indication is:

Treatment of hypotension in haemodynamically unstable neonates, infants and children < 18

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] Hybrid applications rely in part on the results of pre-clinical tests and clinical trials for a reference product and in part on new data.

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years.

Neoatricon should be prescribed by a paediatric specialist or paediatric intensive care specialists to whom facilities are available for monitoring cardiovascular and renal indices, including blood volume, cardiac output, blood pressure, electrocardiography and urine flow.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.