LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Salbutamol Neutec
(salbutamol sulfate)

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salbutamol sulfate

Nebuliser solution, 2,5 mg

This is a summary of the public assessment report (PAR) for Salbutamol Neutec. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Salbutamol Neutec and what is it used for?
The product is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance.

The reference medicine for the product is Ventolin 1 mg/ml, nebuliser solution.

The company has provided additional own data to demonstrate therapeutic equivalence between the product and the reference medicine.

Salbutamol Neutec is used to treat breathing problems in people with asthma and other lung conditions that cause narrowing of the airways (such as chronic obstructive pulmonary disease). They are usually given to people who suffer seriously from these conditions when other forms of treatment do not seem to work. Salbutamol Neutec can be used to treat adults, adolescents, and children aged 4 to 11 years.

Salbutamol Neutec is provided in a small plastic container that contains a liquid. The liquid is put into a machine called a nebuliser. This machine makes a fine mist to breathe in through a face mask.

How does Salbutamol Neutec work?
Salbutamol Neutec contains a medicine called salbutamol. This belongs to a group of medicines called short and fast-acting bronchodilators. Bronchodilators help the airways in your lungs to stay open. This makes it easier for air to get in and out. They help to relieve chest tightness, wheezing and cough.

How is Salbutamol Neutec used?
The pharmaceutical form is nebuliser solution for inhalation.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Salbutamol Neutec have been shown in studies?
Because the product is a hybrid application and is considered to be therapeutically equivalent to the reference product Ventolin, the benefits and risks are taken as being the same as those of the reference medicine.

What are the possible side effects from Salbutamol Neutec?
For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Salbutamol Neutec approved?
It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and similar to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Ventolin, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Salbutamol Neutec?
A risk management plan has been developed to ensure that the product is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Salbutamol Neutec
The full PAR for Salbutamol Neutec can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Salbutamol Neutec, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2023-05.