

Summary Public Assessment Report

Budesonide Pavese (budesonide)

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budesonide

Nebuliser suspension, 0,25 mg/ml, 0,5 mg/ml

This is a summary of the public assessment report (PAR) for Budesonide Pavese. 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 Budesonide Pavese 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 Pulmicort.

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

The product is used to:

- treat, reduce and prevent inflammation of the respiratory tract in asthma,
- treat symptoms of chronic obstructive pulmonary disease (COPD) by reducing inflammation in the airways,
- treat very severe false croup (inflammation of the larynx that can cause difficulty breathing).

How does Budesonide Pavese work?

Budesonide Pavese belongs to a group of drugs called corticosteroids (cortisone). They are used to reduce inflammation.

How is Budesonide Pavese used?

The pharmaceutical form is nebuliser suspension for oral use.

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 Budesonide Pavese have been shown in studies?

Because the product is a hybrid application and is considered to be therapeutically equivalent to the reference product Pulmicort, the benefits and risks are taken as being the same as those of the reference medicine.

What are the possible side effects from Budesonide Pavese?

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 Budesonide Pavese approved?

The Swedish Medical Products Agency decided that 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 Budesonide Pavese?

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 Budesonide Pavese

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

This summary was last updated in 2023-01.