LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Budaxiro
(budesonide)

SE/H/2359/01/DC

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@lakemedelsverket.se

Summary Public Assessment Report

Budaxiro
budesonide

Modified-release capsule, hard, 3 mg

This is a summary of the public assessment report (PAR) for Budaxiro. 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 Budaxiro 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 Entocort®.

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

The product is used to treat Crohn's disease of the small intestine and the first part of the large intestine. Crohn's disease is an inflammatory disease of the bowel that causes symptoms in the form of diarrhoea, fever and stomach pain.
The product is used to treat microscopic colitis, which is a disease producing chronic inflammation of the colon and often resulting in watery diarrhoea. The product can be used to treat both active illness as well as in severe cases to prevent recurring problems (maintenance treatment).

How does Budaxiro work?
The product reduce inflammation in the small intestine and the first part of the large intestine.

How is Budaxiro used?
The pharmaceutical form is modified-release capsule, hard 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 Budaxiro have been shown in studies?
Because the product is a hybrid application and is considered to be therapeutically equivalent to the reference product Entocort®, the benefits and risks are taken as being the same as those of the reference medicine.

What are the possible side effects from Budaxiro?
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 Budaxiro approved?
It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be therapeutically equivalent to the reference medicine.

Therefore, the Swedish Medical Products Agency decided that, as for Entocort®, 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 Budaxiro?
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 Budaxiro
The full PAR for Budaxiro can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Budaxiro , please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2024-03.