LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Budesonid DOC
(budesonide)

SE/H/2219/01/DC

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Summary Public Assessment Report

Budesonid DOC
budesonide

Modified-release capsule, hard, 3 mg

This is a summary of the public assessment report (PAR) for Budesonid DOC. It explains how Budesonid DOC was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Budesonid DOC.

For practical information about using Budesonid DOC, patients should read the package leaflet or contact their doctor or pharmacist.

What is Budesonid DOC and what is it used for?

Budesonid DOC is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance.

The reference medicine for Budesonid DOC is Entocort.

Budesonid DOC is used to:

- reduce inflammation in the small intestine and the first part of the large intestine.
- 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.
- treat microscopic colitis, which is a disease producing chronic inflammation of the colon and often resulting in watery diarrhoea.
- treat both active illness as well as in severe cases to prevent recurring problems (maintenance treatment).

How is Budesonid DOC used?

The pharmaceutical form of Budesonid DOC 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 Budesonid DOC have been shown in studies?

The Swedish Medical Products Agency decided that Budesonid DOC's benefits are greater than its risks and recommended that it can be approved for use.

What are the possible side effects from Budesonid DOC?

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 Budesonid DOC approved?

It was concluded that, in accordance with EU requirements, Budesonid DOC has been shown to have comparable quality and similar to the reference medicine Entocort. 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 Budesonid DOC?

A risk management plan has been developed to ensure that Budesonid DOC 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 for Budesonid DOC, 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 Budesonid DOC

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

This summary was last updated in 2022-07.