LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Mesalazin ESPL
(mesalazine)

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mesalazine

Suppository, 1 g

This is a summary of the public assessment report (PAR) for Mesalazin ESPL. It explains how Mesalazin ESPL 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 Mesalazin ESPL.

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

What is Mesalazin ESPL and what is it used for?

Mesalazin ESPL is a 'hybrid medicine'. This means that it is similar to a reference medicine already authorised in the European Union (EU).
The reference medicine for Mesalazin ESPL is Salofalk, and these products contain the same active substance.

Mesalazin ESPL 1 g Suppositories are used for the treatment of acute mild to moderate ulcerative colitis limited to the rectum (ulcerative proctitis).

How does Mesalazin ESPL work?

Mesalazin ESPL 1 g Suppositories contain the active substance mesalazine, an anti-inflammatory agent used to treat inflammatory bowel disease.

How is Mesalazin ESPL used?

The pharmaceutical form of Mesalazin ESPL is suppository for rectal 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 Mesalazin ESPL have been shown in studies?

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

What are the possible side effects of Mesalazin ESPL?

For the full list of all side effects reported with Mesalazin ESPL, see section 4 of the package leaflet.

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

Why is Mesalazin ESPL approved?

It was concluded that, in accordance with EU requirements, Mesalazin ESPL has been shown to have comparable quality and is considered to be therapeutically equivalent to the reference medicine Salofalk. Therefore, the Medical Products Agency in Sweden decided that, as for Salofalk, 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 Mesalazin ESPL?

A risk management plan has been developed to ensure that Mesalazin ESPL 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 Mesalazin ESPL, 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 Mesalazin ESPL

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

This summary was last updated in YYYY-MM.