

Summary Public Assessment Report

Mesalazin ESPL (mesalazine)

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(mesalazine)

modified-release tablet; 1600 mg

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 containing the same active substance, but is available as modified-release tablets and also in a different strength. The reference medicine for Mesalazin ESPL is Asacol 400 mg gastro-resistant tablet.

The company has provided additional own data to demonstrate the safety and efficacy of Mesalazin ESPL regarding this difference from the reference medicine.

Mesalazin ESPL is used in the treatment of ulcerative colitis.

How does Mesalazin ESPL work?

Mesalazine ESPL contains the active substance mesalazine. It is an anti-inflammatory medicine used for the treatment of ulcerative colitis. Ulcerative colitis is a disease in which the lining of the large intestine (colon) or the back passage (rectum) becomes inflamed (red and swollen). This may lead to frequent and bloody stools, often with abdominal cramps. Mesalazine ESPL treats and prevents inflammation throughout the entire colon and rectum (mild to moderate acute ulcerative colitis and for the prevention of relapse).

How is Mesalazin ESPL used?

The pharmaceutical form of Mesalazin ESPL is modified-release tablet 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.

What benefits of Mesalazin ESPL have been shown in studies?

Because Mesalazin ESPL is a hybrid application of Asacol, clinical studies have been provided for Mesalazin ESPL to show efficacy for the difference of Mesalazin ESPL from the reference product Asacol.

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?

This medicine is similar to a reference medicine containing the same active substance, but is available as modified-release tablets and also in a different strength.

The company has provided additional own data to demonstrate the safety and efficacy of Mesalazin ESPL regarding this difference from the reference medicine.

No new or unexpected safety concerns arose from the application. Therefore, the Medical Products Agency in Sweden decided that Mesalazin ESPL's benefits are greater than its risks and recommended that it 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 marketing authorisation for Mesalazin ESPL was granted on 2018-02-19 in Sweden.

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 2018-02-19.