LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Prednisolon Unimedic
(prednisolone sodium phosphate)

Prednisolon Unimedic Public AR

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

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prednisolone sodium phosphate

Rectal solution, 31,25 mg

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

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

What is Prednisolon Unimedic and what is it used for?

Prednisolon Unimedic is a 'hybrid medicine'. This means that it is similar (*therapeutically equivalent*) to a reference medicine containing the same active substance.

The reference medicine for Prednisolon Unimedic is Pred-Clysma, 31.25 mg rectal solution. Prednisolon Unimedic is used in the treatment of moderate or severe ulcerative proctosigmoiditis (ulcerative inflammation of the large intestine), particularly for the treatment of acute exacerbations in the lower part of the large intestine or rectum.

How does Prednisolon Unimedic work?

Prednisolon Unimedic is a cortisone preparation which reduces inflammation, allergic reactions and lowers the immunogenic response.

How is Prednisolon Unimedic used?

The pharmaceutical form of Prednisolon Unimedic is rectal solution to be inserted in the rectum.

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 be obtained with a prescription in Sweden.

What benefits of Prednisolon Unimedic have been shown in studies?

Because Prednisolon Unimedic is a hybrid application and is considered to be therapeutically equivalent, to the reference product Pred-Clysma, 31.25 mg rectal solution, their benefits and risks are taken as being the same as those of the reference medicine.

What are the possible side effects of Prednisolon Unimedic?

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

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

Why is Prednisolon Unimedic approved?

This medicine is similar (*therapeutically equivalent*) to a reference medicine containing the same active substance. Since Prednisolon Unimedic 31.25 mg rectal solution can be claimed to be identical to the reference product PredClysma 31.25 mg rectal solution, no additional studies were performed within this application. No new or unexpected safety concerns arose from the application. Therefore, the Medical Products Agency in Sweden decided that Prednisolon Unimedic'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 Prednisolon Unimedic?

A risk management plan has been developed to ensure that Prednisolon Unimedic 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 Prednisolon Unimedic, 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 Prednisolon Unimedic

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

This summary was last updated in 2020-02.