LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Prednisolon G.L. Pharma (prednisolone)

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prednisolone

Tablet, 5 mg

This is a summary of the public assessment report (PAR) for Prednisolon G.L. Pharma. 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 Prednisolon G.L. Pharma and what is it used for?
The product is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Prednisolon Pfizer.

The product is used in conditions where you must suppress the body's reaction, such as e.g. the inflammatory reaction in joint rheumatism *(rheumatoid arthritis)*. Other examples that can be mentioned are connective tissue disease *(SLE)*, inflammation of vessel walls, connective tissue changes, asthma, severe inflammation of the large intestine *(ulcerative colitis)*, in certain blood diseases, severe allergic conditions and tumour treatment.

How does Prednisolon G.L. Pharma work?
Prednisolon G.L. Pharma is a cortisone preparation that counteracts and alleviates allergic complaints, inflammations and rheumatic complaints.

How is Prednisolon G.L. Pharma used?
The pharmaceutical form is 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 in Sweden.

What benefits of Prednisolon G.L. Pharma have been shown in studies?

No additional studies were needed as the product is a generic medicine considered to be bioequivalent to the reference medicine, Prednisolon Pfizer. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Prednisolon G.L. Pharma?

Because the product is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

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 Prednisolon G.L. Pharma 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 Prednisolon Pfizer, 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 Prednisolon G.L. Pharma?
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 Prednisolon G.L. Pharma
The full PAR for Prednisolon G.L. Pharma can be found on the following website: MRI - Home. For more information about treatment with Prednisolon G.L. Pharma, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2025-11.