

Summary Public Assessment Report

Teriflunomide Genepharma (teriflunomide)

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Teriflunomide Genepharm
teriflunomide

Film-coated tablet, 7 mg, 14 mg

This is a summary of the public assessment report (PAR) for Teriflunomide Genepharm. 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 Teriflunomide Genepharm 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 AUBAGIO.

The product is used in adults and in children and adolescents (10 years of age and older) to treat relapsing remitting multiple sclerosis (MS).

How does Teriflunomide Genepharm work?

The product helps to protect against attacks on the central nervous system by the immune system by limiting the increase of some white blood cells (lymphocytes). This limits the inflammation that leads to nerve damage in MS.

How is Teriflunomide Genepharm used?

The pharmaceutical form is film-coated table 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 Teriflunomide Genepharm have been shown in studies?

Because the product is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, AUBAGIO. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Teriflunomide Genepharm?

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 Teriflunomide Genepharm approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for AUBAGIO, 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 Teriflunomide Genepharm?

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 Teriflunomide Genepharm

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

This summary was last updated in 2023-12.