LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Diklofenak Mimer
(diclofenac diethylamine)

SE/H/2259/01/MR

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diclofenac diethylamine

Gel, 23,2 mg/g

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

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

What is Diklofenak Mimer and what is it used for?

Diklofenak Mimer is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance.

The reference medicine for Diklofenak Mimer is Voltaren.

Diklofenak Mimer is used in the treatment of mild to moderate pain in connection with muscle and joint injuries, such as sports injuries.

How does Diklofenak Mimer work?

Diklofenak Mimer contains the active substance diclofenac, which belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). Diclofenac relieves pain and has an anti-inflammatory effect.

How is Diklofenak Mimer used?

The pharmaceutical form of Diklofenak Mimer is a gel for cutaneous use only.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

A prescription might be needed for this medicine in Sweden.

What benefits of Diklofenak Mimer have been shown in studies?

Studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine Voltaren.

Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Diklofenak Mimer?

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 Diklofenak Mimer approved?

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

A risk management plan has been developed to ensure that Diklofenak Mimer 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 Diklofenak Mimer, 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 Diklofenak Mimer

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

This summary was last updated in 2022-08.