

Package leaflet: Information for the user

Diklofenak Mimer 23.2 mg/g gel diclofenac diethylamine

[For medicines available only on prescription:]

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

[For medicines available without prescription:]

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

What is in this leaflet

1. What [Product name] is and what it is used for
2. What you need to know before you use [Product name]
3. How to use [Product name]
4. Possible side effects
5. How to store [Product name]
6. Contents of the pack and other information

1. What [Product name] is and what it is used for

[Product name] 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.

[Product name] is used for:

- treatment of mild to moderate pain in connection with muscle and joint injuries, such as sports injuries.

[Product name] is for cutaneous use only.

[For medicines available without prescription:]

You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

2. What you need to know before you use [Product name]

Do not use [Product name]

- If you are allergic to diclofenac or any of the other ingredients of this medicine (listed in section 6).
- If you are allergic to other medicines used to treat pain, fever or inflammation, such as ibuprofen or acetylsalicylic acid (also used to prevent blood clots). If you are not sure, ask your doctor or pharmacist.

- Symptoms of an allergic reaction to these medicines may include: wheezing or shortness of breath (asthma); hives or rash; swelling of the face or tongue; runny nose.
- During the last three months of pregnancy.
- If you are younger than 14 years.

Warnings and precautions

- Talk to your doctor before starting treatment with [Product name] if you have impaired kidney, heart or liver function or gastric ulcers.
- [Product name] must not be used on open wounds, eczema, acne or infected skin.
- Do not use more gel than recommended or for a long period of time as the risk of side effects may increase.
- [Product name] is for cutaneous use only. Do not use it in the mouth or on mucous membranes. [Product name] must never be swallowed.
- Avoid getting [Product name] in your eyes. If this happens, rinse your eyes thoroughly with clean water. Contact your doctor or pharmacist if symptoms persist.
- Wash your hands after use (unless they are the area to be treated) to avoid accidental contact with the mouth and eyes.
- Do not use [Product name] with airtight bandages. When sprained, the joint can be supported by bandage, but the winding must not be so hard that the blood circulation is stopped.
- Avoid direct sunlight and sunbeds during treatment and 2 weeks thereafter, e.g. by covering the treated area with clothing.
- Stop treatment if skin rash occurs.

If you have any questions talk to your doctor or pharmacist before using [Product name].

Children and adolescents

Information on efficacy and safety in the treatment of children and adolescents under 14 years of age is limited (see section “Do not use [Product name]”).

[For medicines available without prescription:]

For children who are 14 years and older, it is recommended that the patient/parents of the child consult a doctor if the condition does not improve within 7 days in case of pain or if symptoms worsen.

Other medicines and [Product name]

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Do not use [product name] if you are in the last 3 months of pregnancy. You should not use [product name] during the first 6 months of pregnancy unless clearly necessary and advised by your doctor. If you need treatment during this period, the lowest dose for the shortest time possible should be used. Oral forms (e.g. tablets) of [product name] can cause adverse effects in your unborn baby. It is not known if the same risk applies to [product name] when it is used on the skin.

Diclofenac passes into breast milk in small amounts. When breast-feeding [Product name] should only be used at the doctor's prescription. [Product name] should not be applied to the breasts of breast-feeding mothers or elsewhere on large areas of skin or for a long period of time.

Driving and using machines

[Product name] has no influence on the ability to drive or use machines.

[Product name] contains propylene glycol and butylhydroxytoluene

Propylene glycol may cause skin irritation and butylhydroxytoluene may cause local skin reactions (eg contact dermatitis) or irritation to the eyes and mucous membranes.

3. How to use [Product name]

[For medicines available only on prescription:]

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

[For medicines available without prescription:]

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Adults and adolescents 14 years of age and over

Dosage: 2 to 4 g (5 to 10 cm gel strand) is applied twice a day. Do not use more than 8 g per day.

[For medicines available without prescription:]

Contact a doctor if symptoms worsen or do not improve within 7 days.

The duration of treatment **should not** be longer than 14 days unless recommended by a doctor.

1. Before first use: remove the seal using the embossed surface on the back of the screw cap.
2. Gently massage the gel into the skin on the painful or swollen area. You may experience a slight cooling sensation when the gel is massaged in.
3. Wipe off excess gel from your hands with an absorbent paper (eg paper towels) or wet wipe and then wash your hands to avoid accidental contact with your mouth and eyes, unless your hands are the site to be treated. If too much gel is accidentally applied, the excess gel should be wiped with a paper towel. The absorbent paper or wet wipe should be discarded in the waste bin after use to prevent unused product reaching the aquatic environment. Before applying a bandage, the gel should be left to dry for a few minutes on the skin.

[Product name] should only be used on the skin.

[Product name] should not be used in children and adolescents below 14 years of age.

If you use more [Product name] than you should

If you have used too much medicine or if, for example, a child has ingested the medicine by accident, contact a doctor or hospital for information of the risks and advice.

If you forget to use [Product name]

If you forgot to use [Product name], apply the next dose when you remember and then continue as usual. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The side effects are usually mild and transient local skin reactions at the site of treatment.

Stop using [Product name] and contact a doctor or emergency **immediately** if swelling of e.g. the face, tongue and/or throat or hives, shortness of breath and difficulty swallowing occurs. This could be a very serious allergic reaction which is a very rare adverse reaction.

Common

(may affect up to 1 in 10 people)

- Rash, eczema, itching, reddening of the skin, inflammation of the skin and stinging sensation in the skin where the gel has been applied.

Rare

(may affect up to 1 in 1,000 people)

- Inflammation of the skin with or without blistering where the gel has been applied.

Very rare

(may affect up to 1 in 10,000 people)

- Photosensitivity reactions in the skin (manifests as sun damage with burning, itching, swelling and blistering), asthma, rash with swollen blisters, hypersensitivity reactions and angioedema (swelling of the skin and mucous membranes, eg in the face and finger joints).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#).^{*} By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Product name]

Keep this medicine out of the sight and reach of children.

This medicine does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the box after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information**What [Product name] contains**

The active substance is diclofenac diethylamine. 1 g of gel contains 23.2 mg (2.32%) diclofenac diethylamine, which corresponds to 20 mg diclofenac sodium.

The other ingredients are: butylhydroxytoluene, carbomer, cocoyl caprylocaprate, diethylamine, isopropyl alcohol, liquid paraffin, macrogol cetostearyl ether, oleyl alcohol, propylene glycol, perfume and purified water.

What [Product name] looks like and contents of the pack

[Product name] is a viscous white gel with characteristic smell.

[Product name] is available in tubes with 30, 50, 60, 100, 120, 150 and 180 g.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer**Marketing Authorisation Holder**

<[To be completed nationally]>

Manufacturer

<[To be completed nationally]>

This medicine is authorised in the Member States of the European Economic Area under the following names:

Sweden	Diklofenak Mimer 23.2 mg/g gel
The Netherlands	Diclofenac Linn 2,32% extra sterk, gel

This leaflet was last revised in 6-Dec-2024