

Package leaflet: Information for the user

Diclofenac STADA® 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 or pharmacist.
- 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 or pharmacist. 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 using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist 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 or pharmacist. 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:

- mild to moderate pain in muscle and joint injuries, e.g. sports injuries.

<Product name> is only intended for cutaneous use.

[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 that are used to treat pain, fever or inflammation, such as ibuprofen or acetylsalicylic acid (also used to prevent blood clots). Ask your doctor or pharmacist if you are not sure.

Symptoms of an allergic reaction to these medicines may include:

- wheezing or shortness of breath (asthma); hives or a rash; swelling of the face or tongue; runny nose.
- If you are in the last 3 months of pregnancy.
- If you are under 14 years of age.

Warnings and precautions

- Consult your doctor before using <Product name> if you have reduced kidney, heart or liver function, or stomach ulcers.
- Do not use <Product name> on open wounds, eczema, acne or infected skin.
- Do not use more gel than recommended or for longer periods of time, as the risk of side effects may increase.
- <Product name> is only intended for cutaneous use. Do not use in the mouth or on mucous membranes. <Product name> must never be swallowed.
- Avoid getting <Product name> in your eyes. If this happens, flush your eyes thoroughly with clean water. Contact your doctor or pharmacist if the symptoms persists.
- Wash your hands after use (unless these are being treated) to avoid accidental contact with your mouth and eyes.
- Do not use <Product name> with an airtight bandage. Sprained joints may be bandaged, but not so tightly that it stops blood flow.
- Avoid direct sunlight and artificial sun during the treatment and for 2 weeks after stopping treatment, e.g. by covering the treated area with clothing.
- Stop the treatment if a rash develops.

Talk to your doctor or pharmacist if you have any questions before using <Product name>.

Children and adolescents

There is limited efficacy and safety data about the treatment of children and adolescents under the age of 14 (see the "Do not use <Product name>" section).

[For medicines available without prescription:]

For children aged 14 and over, it is recommended that the patient/child's parents consult a doctor if the pain does not improve after 7 days or if the symptoms worsen.

Other medicines and <Product name>

Tell your doctor or pharmacist if you are taking, have recently taken or might take 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 diclofenac 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. <Product name> should only be used during breast-feeding on the advice of a doctor. <Product name> should not be applied on the

breasts of nursing mothers nor elsewhere on large areas of skin or for a prolonged period of time.

Driving and using machines

<Product name> has no influence on the ability to drive or to use machines.

<Product name> contains propylene glycol and butylated hydroxytoluene

Propylene glycol may cause skin irritation and butylated hydroxytoluene may cause local skin reactions (e.g. 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 or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults and adolescents 14 years and over

Dosage: Apply 2 to 4 g (a gel strip of 5 to 10 cm) 2 times daily. Do not use more than 8 g per day.

[For medicines available without prescription:]

Talk to your doctor if your symptoms worsen or do not improve after 7 days.

Do **not** use for more than 14 days except on the advice of a doctor.

Method of administration

<Product name> must only be used on the skin.

1. Before using for the first time: open the safety seal using the embossed surface on the back of the screw cap.
2. The gel is applied to the affected parts of the body and gently rubbed into the skin. You may experience a slight cooling effect when the gel is massaged in.
3. Afterwards, wipe off the rest of the gel from your hands using a paper towel and then wash your hands to avoid accidental contact with the mouth and eyes, unless the hands are the site being treated. The paper towel should be disposed in the household waste to prevent unused product reaching the aquatic environment.

<Product name> must not be used by children and adolescents under the age of 14.

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 forget to use <Product name>, apply the next dose when you remember and then continue as usual. Do not use a double dose to make up for a forgotten one.

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

4. Possible side effects

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

The most common side effects are mild and temporary skin reactions at the treatment site.

Stop using <Product name> and contact your doctor **immediately** or go to the nearest emergency if you experience any swelling of e.g. your face, tongue and/or throat or hives, shortness of breath or difficulty swallowing. This may be a serious allergic reaction, which is a very rare side effect.

Common (may affect up to 1 in 100 people)

- Skin rash, eczema, itching, skin redness, skin inflammation and a stinging sensation in the skin where the gel was applied.

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

- Skin inflammation with or without blistering where the gel was applied.

Very rare (may affect up to 1 in 10 000 people)

- Skin photosensitivity reactions (manifest as sun damage, with burning, itching, swelling and blistering), asthma, rash with pus-filled blisters, hypersensitivity reactions and angioedema (swelling of skin and mucous membranes, e.g. 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 package 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 corresponding to 20 mg diclofenac sodium.

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

What <Product name> looks like and contents of the pack

<Product name> is a viscous white gel with a characteristic odour.

<Product name> comes in tubes of 30, 50, 60, 100, 120, 150 and 180 g.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

<to be completed nationally>

Manufacturer

<to be completed nationally>

This leaflet was last revised in 12-DEC-2024