

Diclofenac 1%, gel

Diclofenac sodium

What is Diclofenac 1% and what is it used for?

Diclofenac 1% is a gel specifically designed for topical application to the skin. The active substance, diclofenac, belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). Diclofenac 1% is used for local relief of mild to moderate joint pain caused by exacerbation of knee or finger osteoarthritis. Pain relief from Diclofenac 1% gradually builds up during the first week of treatment.

When should you not use this medication or be extra cautious?

When should you not use this medication?

- You have ever had an allergic reaction to diclofenac or other medicines used to treat pain, fever, or inflammation, such as ibuprofen or acetylsalicylic acid (a medicine also used to prevent blood clotting). If you are unsure, ask your doctor or pharmacist. Symptoms of an allergic reaction to these medicines may include: episodic breathlessness due to muscle spasms and swelling of the mucous membranes of the airways often accompanied by coughing and expectoration of mucus (asthma), wheezing or shortness of breath, severe itching and formation of bumps on the skin, swollen face or tongue, runny nose.
- You are allergic to any of the ingredients in this medicine.
- During the third trimester of pregnancy.

When should you be extra cautious with this medication?

Do not apply to large skin surfaces or for an extended period, unless under medical advice.

- Do not apply this medication to open wounds or damaged skin. Do not apply this medication to skin with eczema or areas with hypersensitivity patches. Discontinue use of this medication if you develop a skin rash.
- This medication can be used with non-occlusive (non-air and non-watertight) dressings, but should not be used under an occlusive (air and watertight) dressing. If necessary, seek advice from your doctor, pharmacist, or drugstore.
- Make sure you avoid getting this medication in your eyes or on mucous membranes (e.g., mouth). Do not ingest or swallow it.

Since this medication is applied to the skin of the affected area, there is a risk of absorption into the bloodstream, resulting in effects in other parts of the body besides the application site. The risk of experiencing such effects depends, among other factors, on the size of the treated area, the amount applied, and the duration of treatment.

Are you taking any other medications?

If you are using any other medications in addition to Diclofenac 1%, have recently used any, or are planning to use other medications in the near future, inform your doctor or pharmacist.

There is a possibility that Diclofenac 1% may alter the effects of other medications you are taking. However, since Diclofenac 1% only enters the bloodstream in small amounts, it is unlikely to interfere with the function of other medications.

Pregnancy and breastfeeding

Are you pregnant, think you might be pregnant, planning to become pregnant, or breastfeeding? Contact your doctor or pharmacist before using this medication. This medication should not be used during the last 3 months of pregnancy, as it may harm your unborn baby or cause complications during delivery. This medication should only be used under medical supervision during the first 6 months of pregnancy.

Like other NSAIDs, this medication may make it more difficult to conceive. If you plan to become pregnant or have experienced difficulties getting pregnant in the past, it is better to avoid using this medication.

If diclofenac is used by a woman who is trying to conceive or during the first 6 months of pregnancy, the dosage should be kept as low as possible, and the duration of treatment should be as short as possible.

This medication should only be used under medical supervision while breastfeeding, as diclofenac passes into breast milk in small amounts. However, this medication should not be applied to the breasts of nursing mothers or to large skin surfaces for an extended period.

Consult your doctor or pharmacist for more information if you are pregnant or breastfeeding.

Driving and using machinery

This medication does not affect your ability to drive or operate machinery.

How to use this medication?

Always use this medication exactly as described in this leaflet or as instructed by your doctor or pharmacist. If you are unsure about the correct usage, contact your doctor or pharmacist.

Adults: Apply this medication 4 times a day to the area of the knee or hand that is experiencing pain.

How to apply this medication?

Gently rub a small amount of this medication onto the skin where you have pain. The required amount may vary depending on the size of the affected area. Normally, an amount roughly the size of a cherry to a walnut will be sufficient. You may experience a mild cooling effect when rubbing in the gel.

Wash your hands after using this medication, unless your hands are the area being treated.

How long should you use this medication?

Do not use this medication for longer than 3 weeks. Pain relief gradually builds up during the first week of treatment. If the pain does not improve within 7 days or worsens, consult your doctor.

In case of accidental contact with this medication: Do not apply this medication to damaged or infected skin.

In case of accidental contact with the eyes, mucous membranes (such as the mouth), or damaged skin, rinse the affected area with running water. Contact your doctor or pharmacist if irritation persists.

In case of accidental or intentional ingestion of this medication: Consult your doctor or pharmacist as soon as possible if you have swallowed this medication.

Have you used too much of this medication?

The risk of overdose cannot be ruled out when applying this medication to large skin surfaces for an extended period (see product information for systemic forms of diclofenac).

Did you forget to use this medication?

Do not worry if you forget to apply this medication once. In this situation, continue using it as you normally would and at the usual time.

If you stop using this medication: The treatment can be stopped at any time without any special precautions.

Possible side effects: Like any medication, this medication can have side effects, although not everyone experiences them.

Immediately stop treatment with this medication and contact your doctor immediately if you experience the following side effects:

- Hypersensitivity, which is a type of allergic reaction manifested as skin rash (skin eruptions with redness), shortness of breath, and difficulty swallowing.
- Bullous reactions (extensive changes in the skin with redness, peeling, and large blisters). This risk appears to be highest at the beginning of treatment, and in most cases, these reactions occur during the first month of treatment.

Common side effects (occur in less than 1 in 10 users): Skin rash, eczema, skin inflammation (dermatitis), and inflammation of the skin due to contact with irritants or substances causing hypersensitivity (contact dermatitis), itching (pruritus).

Rare side effects (occur in less than 1 in 1,000 users): Skin inflammation with blisters (bullous dermatitis), including severe allergic reaction with high fever, skin blisters, joint pain, and/or eye inflammation (Stevens-Johnson syndrome), and severe sudden allergic reaction with symptoms such as fever, skin blisters, and skin peeling (toxic epidermal necrolysis).

Very rare side effects (occur in less than 1 in 10,000 users): Hypersensitivity (including skin rash with severe itching (urticaria) and formation of hives (angioedema)), sudden accumulation of fluid in the skin and mucous membranes (e.g., throat or tongue), difficulty breathing, and/or itching and skin rash often as an allergic reaction (angioedema), intermittent breathlessness due to spasms of the respiratory muscles and swelling of the respiratory mucosa (asthma), rash with pustules (pustular rash), hypersensitivity to light or sunlight (photosensitivity), excessive flushing and redness of the skin (erythema).

Unknown frequency (based on available data, the frequency cannot be determined): Prolonged use of this medication on relatively large areas can cause systemic reactions such as nausea, vomiting, diarrhea, and abdominal pain (epigastric pain).

Reporting of side effects: If you experience any side effects, contact your doctor or pharmacist. This also applies to possible side effects not mentioned in this leaflet. You can also report side effects directly to the Netherlands Pharmacovigilance Centre Lareb, website: www.lareb.nl. By reporting side effects, you can help provide more information on the safety of this medication.

How to store this medication?

- After opening the tube, this medication is usable for 3 months.
- Store below 30°C.