Diclofenac 1% Gel

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

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.

What is in this leaflet

1. What Diclofenac 1% Gel is and what it is used for

Diclofenac 1% Gel is a gel containing 10 mg of diclofenac for each gram of gel. Diclofenac is a phenylacetic acid derivative. It leads to inhibition of cyclooxygenase activity, which, then, leads to the inhibition of prostaglandin synthesis and other inflammation mediators.

Diclofenac acts as anti-inflammatory and analgesic agent in the treatment of:
- mild to moderate muscle pains
- contusions
- post-traumatic pain.

Diclofenac 1% Gel is intended to adults and adolescents aged 14 years and over.

2. What you need to know before you use Diclofenac 1% Gel

DO NOT use Diclofenac 1% Gel:
- if you are allergic to diclofenac or any of the other ingredients of this medicine (listed in section 6).
- if you are hypersensitive to acetylsalicylic acid or to other non-steroidal anti-inflammatory drugs (NSAIDs), which may arise as asthma, urticaria or other allergic reactions.
- for children under 14 years of age.
- are in the last 3 months of your pregnancy (see also "Pregnancy and breast-feeding")
- if you have kidney failure.

Warnings and precautions
It is important to know that the occurrence of systemic side effects with the topical use of diclofenac is low when compared with the frequency of side effects with the oral use of diclofenac.

As there is a possibility of Diclofenac 1% Gel cutaneous absorption, it is not possible to exclude the occurrence of systemic effects. The risk of the occurrence of these effects depends, among other factors, on the exposed surface, applied quantity and exposure time.

Cutaneous safety of NSAIDs: It has been reported, very rarely, serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome and toxic epidermal necrolysis, associated with the administration of NSAIDs. Apparently the risk of occurrence of these reactions is greater at the beginning of treatment, and in most cases these reactions are manifested during the first month of treatment.
Diclofenac 1% Gel should be discontinued at the first signs of rash, mucosal lesions or other manifestations of hypersensitivity.
Diclofenac 1% Gel can only be applied on healthy skin (do not apply on open wounds).
Diclofenac 1% Gel cannot come in contact with conjunctive tissue or mucous membranes (for example in mouth). It cannot be ingested.
The area treated with Diclofenac 1% Gel should not be exposed to sunlight.

Other medicines and Diclofenac 1% Gel
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Diuretics, Angiotensin Converting Enzyme Inhibitors (ACE inhibitors) and Angiotensin II Antagonists (AAII): The NSAIDs may decrease the effectiveness of diuretics and other antihypertensive medicines. In some patients with impaired renal function (for example, dehydrated patients or elderly with impaired renal function) the co-administration of an ACE inhibitor or AAII and cyclooxygenase inhibitors may result in the progression of the renal function deterioration, including the possibility of acute renal failure, which is usually reversible. The occurrence of these interactions should be considered in patients using diclofenac, particularly if it is used in large areas of the skin for prolonged periods, in combination with ACE inhibitors or AAII. Consequently, this drug combination should be used with caution, especially in elderly patients. Patients should be properly hydrated and the need to monitor the renal function should be analysed after the beginning of the concomitant therapy and periodically thereafter.
Since systemic absorption of diclofenac from a topical application is very low such interactions are very unlikely.

Diclofenac 1% Gel with food and drink
There are no known interactions of Diclofenac 1% Gel with food and/or drinks.

Pregnancy and breast-feeding
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 taking this medicine.

Pregnancy
Diclofenac 1% Gel must not be used during the last 3 months of pregnancy, as it could harm your unborn child or cause problems at delivery. Diclofenac 1% Gel should only be used under medical advice during the first 6 months of pregnancy and the dose should be kept as low and duration of treatment as short as possible.

Breast-feeding
Diclofenac 1% Gel passes into breast milk in small amounts. However, Diclofenac 1% Gel should not be applied on the breasts of nursing mothers nor elsewhere on large areas of skin or for a prolonged period of time.

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

Driving and using machines
Diclofenac 1% Gel does not affect the ability to drive or use machines.

Diclofenac 1% Gel contains propylparaben, methylparaben and propylene glycol
Diclofenac 1% Gel contains propylparaben (E216) and methylparaben (E218), which may cause allergic reactions, possibly delayed.
Diclofenac 1% Gel also contains propylene glycol which during its topic use may cause skin irritation.

3. How to use Diclofenac 1% Gel

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

Adults and adolescents aged 14 years and over
Apply thin layers of Diclofenac 1% Gel in the affected area, 3 to 4 times daily according to the need of the situation (2-4g, quantity as big as a cherry or a walnut) and rub gently. The treatment duration depends on the indications and on the response to the treatment. It is recommended that the treatment should be evaluated 7 days after its start.

In adolescents aged 14 years and over, if this product is required for more than 7 days for pain relief or if the symptoms worsen the patients/parents of the adolescent is/are advised to consult a doctor.
Diclofenac 1% Gel can be used as additional treatment with the oral administration of non-steroidal anti-inflammatory drugs.

Children under the age of 14 years
Diclofenac 1% Gel must not be used in children under the age of 14 years, since there are no data on the safety and efficacy in this group of patients (see section **2. DO NOT use Diclofenac 1% Gel**).

Patients with liver or kidney insufficiency
No dosage adjustment is necessary in these patients.

Elderly
The usual adult dosage may be used.

Method of administration
Apply on healthy skin only.
After application, wash your hands, unless these are being treated.

In case of accidental contact with Diclofenac 1% Gel
Do not apply Diclofenac 1% Gel to injured or infected skin.
In case of accidental contact with eyes, mucous membranes (for example mouth) or areas of injured skin, rinse the affected area with running water. If the irritation persists, contact your doctor or pharmacist.

In case of accidental or deliberate intake of Diclofenac 1% Gel
Immediately go to a hospital where the adequate therapeutic measures should be implemented. Take the package and the tube with you.

If you use more Diclofenac 1% Gel than you should
Diclofenac is very poorly absorbed into the bloodstream and thus the overdose with topical use is unlikely.
If you or a child accidentally swallows Diclofenac 1% Gel contact your doctor, pharmacist or hospital immediately.

If you forget to use Diclofenac 1% Gel
Do not worry if, occasionally, you forget to apply Diclofenac 1% Gel. In these situations, continue with the applications normally, at the usual time.

If you stop using Diclofenac 1% Gel
The treatment can be stopped at any time, without requiring special care. However, you may feel again pain or swelling in the affected area.

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.

You should immediately stop the treatment with Diclofenac 1% Gel and contact your doctor immediately if you notice the following side effects (may affect up to 1 in 10,000 people):
- hypersensitivity, which is a kind of allergic reaction manifested by cutaneous rash (skin eruption with redness), shortness of breath and difficulty of swallowing;
- wheezing, shortness of breath or feeling of tightness in the chest (asthma)
- swelling particularly of the face, lips and throat (angioedema)

Apparently the risk of these reactions is greater at the beginning of the treatment and, in most cases, these reactions happen during the first month of the treatment.

Diclofenac 1% Gel is well tolerated.

Common (may affect up to 1 in 10 people)
- skin rash
- skin disorder (eczema)
- reddening of the skin (erythema)
- inflammation of the skin in the area of the application that is manifested by rash, swelling or papules (dermatitis, contact dermatitis)
- itching of the skin (pruritus)

Rare (may affect up to 1 in 1,000 people)
- extensive changes in the skin with the appearance of redness, scaling, and large bubbles (bullous dermatitis)

Very rare (may affect up to 1 in 10,000 people)
skin rash with pus-filled blisters (rash pustular)
increased sensitivity of the skin to sunlight (photosensitivity reaction)

Not known
- Burning sensation at the application site
- Dry skin

Prolonged use of Diclofenac 1% Gel in a relatively large area can cause side effects in other areas of the body beyond the skin, such as:
- nausea
- vomiting
- diarrhoea
- stomach pain

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 Yellow

Card Scheme at www.mhra.gov.uk/yellowcard or search for 'MHRA Yellow Card' in the Google play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Diclofenac 1% Gel

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the carton and tube.
The expiry date refers to the last day of that month.
Store below 25°C.

Do not use this medicine if you notice visible signs of deterioration.

After first opening, use the medicinal product for a maximum period of 6 months.

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 Diclofenac 1% Gel contains
The active substance is diclofenac sodium.
The other ingredients are: sodium hydroxide, hydroxyethyl cellulose, carbomers, propylene glycol, medium-chain triglycerides, propylhydroxybenzoate (E216), methylhydroxybenzoate (E218) and purified water.

What Diclofenac 1% Gel looks like and contents of the pack
Diclofenac 1% Gel is packaged in aluminium tubes with a high density polyethylene cap containing 60 g or 100 g of gel.
Diclofenac 1% Gel is packaged in aluminium tubes with polypropylene cap containing 30 g of gel.

Marketing Authorisation Holder and Manufacturer

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