

Package leaflet: Information for the patient

Diclomel Max Strength 2% w/w gel

Diclofenac, corresponding to diclofenac sodium (as diclofenac diethylamine)

For adults and adolescents aged 14 years and over

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 have 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 3-5 days.

What is in this leaflet

1. What Diclomel Max Strength is and what it is used for
2. What you need to know before you use Diclomel Max Strength
3. How to use Diclomel Max Strength
4. Possible side effects
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1. What Diclomel Max Strength is and what it is used for

Diclofenac contains the active substance diclofenac. It belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

For adults and adolescents aged 14 years and over

For the short-term local symptomatic treatment of mild to moderate pain in acute strains, sprains or contusions following blunt trauma.

2. What you need to know before you use Diclomel Max Strength

Do not use Diclomel Max Strength

- if you are allergic to diclofenac or any of the other ingredients of this medicine listed in section 6
- if you have ever developed breathing problems (asthma, bronchospasm), hives, runny nose, or swelling of the face or tongue after taking/using acetylsalicylic acid or another non-steroidal anti-inflammatory drugs (e.g. ibuprofen)
- on open injuries, inflammations or infections of the skin or on eczema and mucous membranes
- in the last three month of pregnancy
- in children and adolescents under 14 years of age

Warnings and precautions

Talk to your doctor or pharmacist before using Diclomel Max Strength.

- If Diclomel Max Strength is applied to large areas of the skin and used over a prolonged period, the possibility of systemic side effects from application of Diclomel Max Strength cannot be ruled out. The gel should therefore be used with caution by patients with reduced kidney function, reduced heart function or reduced liver function as well as patients with active peptic ulcers in the stomach or duodenum.
- Apply Diclomel Max Strength only to intact, not diseased or injured skin. Avoid contact with eyes and oral mucous membranes. The gel must not be taken by mouth.

- After applying the gel on the skin you can use a permeable (non-occlusive) bandage but allow the gel to dry on the skin for a few minutes. Do not use an airtight occlusive dressing.
- If the symptoms worsen or do not improve after 3-5 days, consult a doctor.
- If you suffer from asthma, hay fever, swelling of the nasal membrane (so-called nasal polyps) or chronic obstructive pulmonary disease, chronic respiratory tract infections (particularly associated with hay fever-like symptoms) or hypersensitivity to other painkillers and anti-rheumatic medicines of any kinds, you are more at risk than other patients of asthma attacks (so-called analgesic intolerance / analgesic asthma), local skin or mucous membrane swelling (so-called Quincke oedema) or hives. In this case, Diclomel Max Strength may only be used with certain precautions (emergency preparedness) and under direct medical supervision. The same applies for patients who are also allergic to other substances e.g. with skin reactions, itching or hives.
- The use of Diclomel Max Strength should be discontinued if you develop a skin rash.
- If you are exposed to direct sunlight or artificial sun there is a risk of skin reactions. You should avoid sunlight or artificial sun during treatment and for two weeks after stopping treatment.
- Precautions should be taken to prevent children from touching the area to which the gel is applied.
- Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings, etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

Children and adolescents

Do not use Diclomel Max Strength in children and adolescents under 14 years.

Other medicines and Diclomel Max Strength

Tell your doctor or pharmacist if you are taking, have recently taken or might take/use any other medicines.

If used as advised, no interactions with other medicines have been seen so far.

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 using this medicine.

Pregnancy

During the first six months of pregnancy, Diclomel Max Strength should be used only after consultation with your doctor.

Do not use Diclomel Max Strength during the last three months of pregnancy as an increased risk of complications for mother and child cannot be ruled out.

Breast-feeding

Small amounts of diclofenac pass into breast-milk. Diclomel Max Strength should only be used during breast-feeding after consulting a doctor. Do not apply Diclomel Max Strength on the chest area or on large areas of skin or for a prolonged period of time.

Driving and using machines

Diclomel Max Strength has no or negligible influence on the ability to drive or to use machines.

Diclomel Max Strength contains propylene glycol (E1520), butylhydroxytoluene (E321) and fragrance with allergens

This medicine contains 50 mg propylene glycol in each gram of gel.

Butylhydroxytoluene may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

This medicine contains fragrance with eugenol and citral which may cause allergic reactions.

3. How to use Diclomel Max Strength

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

Adults and adolescents 14 years and over

Dicloamel Max Strength is used 2 times a day (preferably in the morning and evening).

Depending on the size of the painful area to be treated, a cherry to walnut sized amount, corresponding to 1-4 g of gel, is required.

The maximum daily dose is 8 g of gel.

Elderly patients

No special dose adjustment is necessary. If you are elderly, you should pay special attention to side effects and, if necessary, consult a doctor or pharmacist.

Impaired kidney or liver function

No dose reduction is necessary.

Use in children and adolescents (under 14 years)

Dicloamel Max Strength is contraindicated in children and adolescents under 14 years (see section 2 "Do not use Diclomel Max Strength").

Method of administration

Dicloamel Max Strength is for use on the skin only (cutaneous use).

Apply Diclomel Max Strength to the affected parts of the body thinly and rub gently into the skin. It should not be rubbed in with pressure. Afterwards, the hands should be wiped on a paper towel and then washed, unless they are the area being treated. The paper towel should be disposed of in residual waste.

If applying a bandage (see section 2 "Warnings and precautions"), the gel should be allowed to dry for a few minutes on the skin. Similarly, before showering or bathing, wait until the gel has dried on the skin.

Duration of treatment

The duration of use depends on the symptoms and the underlying condition. Diclomel Max Strength should not be used longer than 7 days without medical advice.

If symptoms have not improved or worsen after 3-5 days, a doctor should be consulted.

If you use more Diclomel Max Strength than you should

Due to the low absorption of diclofenac in the total organism with limited application to the skin, an overdose is unlikely to happen.

If the recommended dose is significantly exceeded when used on the skin, the gel should be removed again (e.g. with a paper towel) and the area washed with water.

If you accidentally swallow Diclomel Max Strength, contact your doctor immediately who will decide on appropriate measures.

If you forget to use Diclomel Max Strength

Do not use a double dose to make up for a forgotten application.

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 following side effects can have serious consequences. **Stop using Diclomel Max Strength and contact your doctor or pharmacist immediately.**

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

- skin rash with blisters (dermatitis bullous)

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

- wheezing, shortness of breath or feeling of tightness in the chest (asthma)
- swelling of the face, lips, tongue or throat (angioedema)

Other possible side effects:

Common side effects (may affect up to 1 in 10 people)

- skin rash
- itching
- reddening of the skin (erythema)
- eczema
- dermatitis (inflammation of the skin) including contact dermatitis

Uncommon side effects (may affect up to 1 in 100 people)

- scaling
- drying of the skin
- swelling (oedema)

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

- pustular rash
- gastrointestinal complaints
- hypersensitivity reactions (including hives)
- sensitivity to light with appearance of skin reactions after exposure to sunlight

Not known side effects (cannot be estimated from the available data)

- burning sensation at the application site
- dry skin

When Diclomel Max Strength is applied to a large area of skin and over a prolonged period, the possibility of systemic side effects (e.g. liver, kidney or gastrointestinal side effects, systemic hypersensitivity reactions) - as they occur possibly after systemic administration of diclofenac-containing medicines cannot be completely excluded.

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:

Ireland:

HPRA Pharmacovigilance, Website: www.hpra.ie.

Malta:

ADR Reporting, Website: www.medicinesauthority.gov.mt/adrportal

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Diclomel Max Strength

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 after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not refrigerate or freeze.

After first opening: Do not store above 25°C.

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 Diclomel Max Strength contains

The active substance is diclofenac.

1 g contains diclofenac as 23.2 mg diclofenac diethylamine corresponding to 20 mg diclofenac sodium.

The other ingredients are: propylene glycol (E1520), oleyl alcohol, isopropyl alcohol, butylhydroxytoluene (E321), diethylamine, paraffin light liquid, macrogol cetostearyl ether, carbomer 980, cocoyl caprylocaprate, perfume cream (contains eugenol and citral), purified water.

What Diclomel Max Strength looks like and contents of the pack

White gel

The gel is packed in aluminium laminate tubes sealed with a top seal and closed with a polypropylene screw cap. The product is available in tubes of 30 g, 50 g, 60 g, 100 g, 120 g, 150 g and 180 g.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer

Kern Pharma S.L., Calle Venus 72, Poligono Industrial Colom II 08228 Terrassa, Barcelona, Spain
STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel, Germany
Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

This medicinal product is authorised in the Member States of the EEA under the following names

Belgium:	Diclofenac EG Forte 20 mg/g gel
Bulgaria:	Mobilat Emulgel 2,32% gel
Estland:	Ditel
Germany:	Diclofenac AL Schmerzgel forte 20 mg/g Gel
Ireland:	Diclomel Max Strength 2% w/w gel
Italy:	Diclofenac EG STADA Italia
Latvia:	Ditel 23,2 mg/g gels
Lithuania:	Ditel 23.2 mg/g gelis
Luxembourg:	Diclofenac EG Forte 20 mg/g gel
Malta:	Diclomel Max Strength 2% w/w gel
Poland:	DicloMAX Mobilat

This leaflet was last revised in April 2023.