Package leaflet: Information for the user

Diclomel 140 mg medicated plaster
For use in adolescents from 16 years of age and adults
diclofenac sodium

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 7 days.

What is in this leaflet

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

1. What Diclomel is and what it is used for

Diclomel is a medicine that relieves pain. It belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs).
Diclomel is used for the local symptomatic and short-term treatment (max. 7 days) of pain associated with acute strains, sprains or bruises on the arms and legs as a result of blunt injuries in adolescents from 16 years of age and adults.

2. What you need to know before you use Diclomel

Do not use Diclomel
- if you are allergic to diclofenac or any of the other ingredients in this medicine (listed in section 6)
- if you are allergic to any other non-steroidal anti-inflammatory drug (NSAID, e.g. acetylsalicylic acid or ibuprofen)
- if you have ever developed asthma attacks, hives or swelling and irritation inside the nose after taking acetylsalicylic acid or any other NSAID
- if you are suffering from an active stomach or duodenal ulcer
- on injured skin (e.g. skin abrasions, cuts, burns), infected skin or skin affected by exudative dermatitis or eczema
- if you are in the last three months of pregnancy
- if you are a child or an adolescent younger than 16 years of age.

Warnings and precautions
Talk to your doctor or pharmacist before using Diclomel

- if you suffer or have previously suffered from bronchial asthma or allergies; you may experience a bronchial muscle cramp (bronchospasm), which make breathing difficult
- if you notice a skin rash that develops after applying the medicated plaster. If this happens, immediately remove the medicated plaster and stop treatment
- if you suffer from disorders of the kidneys, heart or liver
- if you have previously suffered from a stomach or intestinal ulcer, intestinal inflammation or a tendency to bleed

Side effects can be reduced by using the lowest effective dose for the shortest possible period of time.

IMPORTANT precautions
- The medicated plaster must not come into contact with or be applied to the eyes or mucous membranes.
- Elderly patients should use Diclomel with caution because they are more likely to experience side effects.

After taking off the medicated plaster, avoid exposing the treated area to direct sunlight or solarium radiation in order to reduce the risk of sensitivity to light.

Do not use Diclomel at the same time as any other diclofenac-containing or other non-steroidal pain-relieving and anti-inflammatory medicines regardless of whether these are used externally or taken by mouth.

Children and adolescents
Diclomel must not be used in children and adolescents under 16 years of age. There are insufficient data of efficacy and safety available for children and adolescents below 16 years (see section Do not use Diclomel).

Other medicines and Diclomel
Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.

Provided that Diclomel is used correctly, only a small amount of diclofenac is absorbed into the body so that the interactions described for diclofenac-containing medicines taken orally are unlikely to happen.

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.

Pregnancy
Do not use Diclomel if you are in the last 3 months of pregnancy. You should not use Diclomel 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 Diclomel when it is used on the skin.

Breast-feeding
Small quantities of diclofenac pass into human milk.

Talk to your doctor before using Diclomel during breast-feeding. In any case, if you are breast-feeding Diclomel should not be applied directly onto the breast area.

Driving and using machines

Diclomel has no influence on your ability to drive and use machines.

3. How to use Diclomel

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.

The recommended dose is one medicated plaster twice daily.

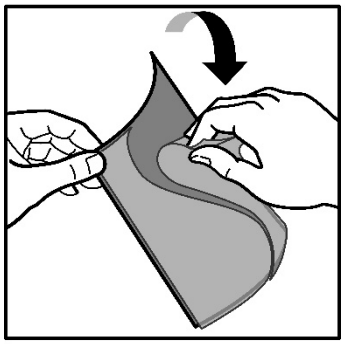
Adults and adolescents aged 16 years and older
Attach one medicated plaster to the painful area twice daily, in the morning and in the evening. The maximum total daily dose is 2 medicated plasters, even if there is more than one injured area to be treated. Treat only one painful area at a time.
Diclomel is to be used for the shortest duration necessary to control symptoms.
If this medicine is required for more than 7 days for pain relief or if the symptoms worsen, it is advised to consult a doctor.

Use in children and adolescents
Diclomel must not be used in children and adolescents under 16 years of age.
There are insufficient data of efficacy and safety available for children and adolescents below 16 years (see section 2).

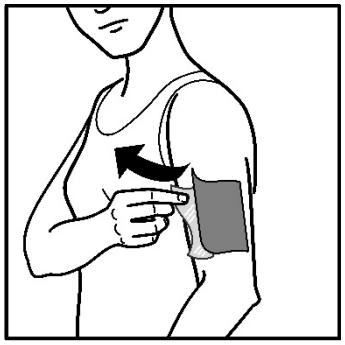
Method of administration
For application on the skin (cutaneous use).

Instructions for use
1. Tear open the envelope containing the medicated plaster on the notch and remove the medicated plaster.

To apply the plaster
2. Remove one of the two protective films.



3. Apply to the area to be treated and remove the remaining protective film.

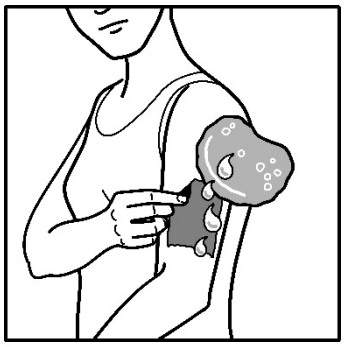


4. Apply slight pressure with the palms of your hand until complete adhesion to the skin is achieved.



To remove the plaster

5. Moisten the plaster with water and peel away an edge of the plaster and pull smoothly away from the skin.



6. To remove any product residues, wash the affected area with water gently rubbing the area with your fingers using a circular movement.

If necessary, the medicated plaster can be held in place using a net bandage.

Use the medicated plaster only on intact non-diseased skin.

Do not use the medicated plaster together with an air-tight (occlusive) bandage.

Do not wear it when bathing or showering.

You should not divide the medicated plaster.

Duration of use

Do not use Diclomel for longer than 7 days.
If symptoms worsen or persist for longer than 7 days, you should consult a doctor.

If you have the impression that the effect of Diclomel is too strong or too weak, please talk to your doctor or pharmacist.

If you use more Diclomel than you should

Please tell your doctor if you experience side effects after incorrect use of this medicine or accidental overdose (e.g. in children). He/she will be able to advise you of any action that may need to be taken.

If you forget to use Diclomel

Do not use 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 or pharmacist.

4. Possible side effects

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

Tell your doctor immediately and stop using the plaster if you notice any of the following:
Sudden itchy rash (hives); swelling of the hands, feet, ankles, face, lips, mouth or throat; difficulty breathing; drop in blood pressure (feeling lightheaded) or weakness.

You may experience the following side effects:

Common (may affect up to 1 in 10 people):
- local skin reactions, including the application site, such as such as eczema (itchy, red and dry skin), skin redness, itching, inflamed skin redness (local allergic reactions and contact dermatitis), skin rash, (sometimes with pustules or wheals)

Rare (may affect up to 1 in 1 000 people)
- redness of the skin with blister or fluid-filled bubbles (dermatitis bullous)
- dry skin

Very rare (may affect up to 1 in 10 000 people):
In patients externally using medicines from the same active substance group as diclofenac, it has been reported:
- isolated reports of generalised skin rash with pustules or papules
- hypersensitivity reactions such as swelling of the skin and mucous membranes and anaphylactic-type reactions with acute circulatory regulation disorders
- light sensitivity reactions
- asthma (breathing difficulties, shortness of breath, wheezing and/or feeling of tightness in the chest)

Not known (frequency cannot be estimated from the available data)
- burning sensation at the application site

Absorption of diclofenac into the body by the skin is very low compared to the drug concentration in the blood following oral use of diclofenac. Therefore, the likelihood of side effects occurring in the body as a whole (such as gastrointestinal, liver or kidney disturbances or difficulty breathing) is very low. However, in particular when the medicated plaster is used on a large area of skin and over a prolonged period of time, systemic side effects may occur.

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

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 outer carton and the sachet after ”EXP”. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Used plasters should be folded in half with the sticky side inwards.

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 contains

The active substance is diclofenac sodium.
Each medicated plaster contains 140 mg diclofenac sodium.

The other ingredients are:

Supporting layer: Polyester non-woven fabric
Adhesive layer: Acrylate copolymer, Basic butylated methacrylate copolymer, Polyethylene glycol stearate, Sorbitan oleate, Levomenthol
Liner: One-sided siliconized PET liner

What Diclomel looks like and contents of the pack
Diclomel is a 100 mm * 140 mm sized rectangular plaster composed of adhesive colourless to pale yellow matrix sandwiched between a white polyester backing and a siliconized transparent release liner.

Diclomel is available in packs of 2, 5, 7 and 10 plasters, each in a single sachet.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer
Laboratori Fundacio DAU, Calle de la Lletra C, 12-14 Polígono Industrial Zona Franca, 08040 Barcelona, Spain
STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel, Germany
Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland
STADA Arzneimittel GmbH, Muthgasse 36/2, 1190 Wien, Austria

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

Austria:	Mobiflex akut Diclofenac 140 mg wirkstoffhaltiges Pflaster
Bulgaria:	Mobilat 140 mg medicated plaster
Czech Republic:	Dicoren
Estonia:	Diclofenac STADA
France:	DICLOFENAC EG 140 mg, emplâtre médicamenteux
Germany:	Diclofenac AL Schmerzpflaster 140 mg wirkstoffhaltiges Pflaster
Ireland:	Diclomel 140 mg medicated plaster
Italy:	Diclofenac EG STADA
Latvia:	Diclofenac STADA 140 mg ārstnieciskais plāksteris
Lithuania:	Diclofenac STADA 140 mg vaistinis pleistras
Malta:	Diclomel 140 mg medicated plaster
Poland:	DoloMobilat patch
Portugal:	Diclofenac STADA

Romania: Diclofenac Stada 140 mg emplastru medicamentos
Slovakia: Elmofen 140 mg liečivá náplasť

This leaflet was last revised in April 2026.