

Package leaflet: Information for the user

Diclofenac 140 mg Medicated Plaster

diclofenac sodium (as diclofenac epolamine)

Read all of this leaflet carefully before you start taking 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

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1. What Diclofenac 140 mg Medicated Plaster is and what it is used for

Diclofenac belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs reduce pain and inflammation.

Diclofenac 140 mg medicated plaster is used to relieve the pain and inflammation of tennis elbow, golfer's elbow and a sprained ankle in adolescents from 16 years of age and adults.

2. What you need to know before you use Diclofenac 140 mg Medicated Plaster

Do not use Diclofenac 140 mg Medicated Plaster:

- if you are allergic to diclofenac, acetylsalicylic acid (aspirin) or any other NSAID
- if you are allergic to any of the other ingredients of this medicine (listed in section 6)
- if you have asthma, breathing problems, skin rash or a runny nose after taking acetylsalicylic acid (aspirin) or other NSAIDs
- if you are entering or are already beyond your 6th month of pregnancy
- if you currently have a stomach ulcer (peptic ulcer)
- if you have any damaged skin including weeping or infected areas, eczema, burns or wounds
- if you are a child or adolescent aged less than 16 years.

If any of the above applies to you talk to your doctor or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist before using this medicine if:

- You have heart disease
- You have kidney disease

- You have liver disease
- You have had stomach ulcers in the past
- You have inflammatory bowel disease such as Crohn's disease or ulcerative colitis or you are susceptible to bleeding from your bowel
- You have asthma
- You have breathing problems, skin rash or a runny nose after taking acetylsalicylic acid (aspirin) or other NSAIDs
- You are taking diclofenac or other NSAIDs, as an oral or topical preparation
- You regularly use a sun-bed or sunbathe
- You are elderly as you may be more prone to side effects.

Children and adolescents

Do not use in case of children or adolescent aged less than 16 years

Other medicines and Diclofenac 140 mg Medicated Plaster

If the medicated plaster is correctly used the risk of interaction with other medicinal products is very low. However, inform your doctor or pharmacist if recently you used or took or you are currently using or taking any other medicines.

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.

Diclofenac medicated plaster must not be used if you are entering or are already beyond your 6th month of pregnancy, as it could harm your unborn child or cause problems at delivery. This medicine should only be used under medical advice before the 6th month of pregnancy and the dose should be kept as low and duration of treatment as short as possible.

This medicine should only be used under medical advice during breast-feeding as diclofenac passes into breast milk in small amounts. However, the medicated plaster 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 medicated plaster application has no influence on the ability to drive and use machines.

This medicine contains

- 420 mg propylene glycol in each medicated plaster.
- Methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause allergic reactions (possibly delayed).
- Fragrance with amyl cinnamal, amylcinnamyl alcohol, benzyl alcohol, benzyl benzoate, benzyl salicylate, cinnamal, cinnamyl alcohol, citronellol, d-Limonene, eugenol, farnesol, geraniol, hexyl cinnamaldehyde, hydroxycitronellal, isoeugenol, linalool, methyl heptene carbonate. These allergens may cause allergic reactions.

3. How to use Diclofenac 140 mg Medicated Plaster

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

Important:

Your doctor will choose the dose that is right for you. Your dose will be shown clearly on the label that your pharmacist puts on your medicine. If it does not, or you are not sure, ask your doctor or pharmacist.

Adults or adolescents 16 years of age and over

How many plasters to use

Tennis elbow or golfer's elbow

- Apply one plaster in the morning
- Remove the plaster in the evening and apply a new one
- Remove the plaster in the morning
- Repeat these steps for a maximum of 14 days.

Ankle sprains

- Apply one plaster per day
- Remove the plaster the next day and apply a new one
- Repeat these steps for a maximum of 3 days.

Remember: Ankle sprains will normally improve within 3 days and elbow pain within 14 days. If they do not, or if your symptoms get worse, tell your doctor.

Use in children and adolescents (under 16 years of age)

There are insufficient data on efficacy and safety available for children and adolescents below 16 years (see Do not use Diclofenac 140 mg Medicated Plaster).

In children aged 16 years and over, if the symptoms worsen, the patient/parents of the adolescent is/are advised to consult a doctor.

How to apply this medicine

- Cut the top off the resealable sachet, take out a plaster and carefully close the seal.
- Record the date on which the sachet was opened in the space provided
- Remove the plastic backing protecting the sticky side of the plaster.
- Apply the plaster to the skin around the painful or swollen area. If necessary, it may be held in place with an open weave gauze bandage or thin strips of tape. These can be obtained from your pharmacist.
- Do not cover the plaster with any other kind of dressing.
- The medicated plaster should be applied only to intact, non-diseased skin, and not to skin wounds or open injuries, and should not be worn when bathing or showering.
- Take care to keep the gel away from your eyes, nose, mouth, genital and anal areas. If gel does come into contact with these, rinse away with water.
- The plaster should not be cut.

If you forget to use Diclofenac 140 mg Medicated Plaster

Do not apply an additional plaster to make up for a missed dose. Simply apply your next plaster as planned.

If you have any further questions about 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.

Some uncommon and very rare side effects might be serious

If you experience any of the following signs of allergy, STOP using this medicine and tell a doctor or a pharmacist immediately:

- **Swelling of the lips, eyes or tongue, wheezing or asthma attack** which are signs of severe allergic reaction (affect less than 1 user in 10,000),
- **Rash, stinging or burning** at the site where the plaster was applied (affect 1 to 10 users in 1,000).

Other side effects which may occur are usually mild, passing and harmless (if you are concerned, tell a doctor or pharmacist).

Common (may affect up to 1 in 10 people)

- Itchy skin

Uncommon (may affect up to 1 in 100 people)

- Skin rash
- Redness of the skin
- Tiny red or purple coloured spots under the skin

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

- Dry scaly skin
- Swelling at the site where the plaster was applied.

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

- Skin rashes made worse by sunlight

Because this medicine is applied to the skin over the affected area, there is less risk of unwanted effects, such as stomach problems including pain, indigestion, or any signs of bleeding in the stomach or intestine, that can occur when diclofenac is taken by mouth. However, if this medicine is not used correctly, these unwanted effects could 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 HPRAs Pharmacovigilance Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side-effects you can help provide more information on the safety of this medicine.

5. How to store Diclofenac 140 mg Medicated Plaster

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

Do not store above 25°C.

Use within 3 months of opening the sachet. After removing each plaster, ensure the sachet is resealed.

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 140 mg Medicated Plaster contains

The active substance is diclofenac epolamine. Each medicated plaster contains a total of 180 mg of diclofenac epolamine, corresponding to 140 mg diclofenac sodium (1% w/w).

The other ingredients are gelatin, povidone (K90), sorbitol liquid, heavy kaolin, titanium dioxide (E171), propylene glycol, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), disodium edetate (E385), tartaric acid, aluminium glycinate, carmellose sodium, sodium polyacrylate, 1,3-butylene glycol, polysorbate 80, fragrance (containing amyl cinnamal, amylcinnamyl alcohol, benzyl alcohol, benzyl benzoate, benzyl salicylate, cinnamal, cinnamyl alcohol, citronellol, d-Limonene, eugenol, farnesol, geraniol, hexyl cinnamaldehyde, hydroxycitronellal, isoeugenol, linalool, methyl heptine carbonate), purified water and unwoven polyester support.

For excipients with known effect see section 2.

What Diclofenac 140 mg Medicated Plaster looks like and contents of the pack

Each medicated plaster consists of a white to pale yellow paste impregnated into a dressing with a removable clear plastic backing protecting an adhesive layer. Resealable sachets contain either 2 or 5 plasters.

This medicine comes in packs of 2, 5, 10 and 14 plasters per box.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

IBSA Farmaceutici Italia Srl
Via Martiri di Cefalonia 2
26900 – Lodi
Italy

Manufacturer

Altergon Italia srl
Zona Industriale
83040 Morra De Sanctis (AV)
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