

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Amgesic Pain Relief 1% Gel

Diclofenac sodium

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

This medicine is available without prescription, however, you still need to use Amgesic Pain Relief 1% Gel carefully to get the best results from it.

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve within 7 days.
- If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Amgesic Pain Relief 1% Gel is and what it is used for
2. What you need to know before you use Amgesic Pain Relief 1% Gel
3. How to use Amgesic Pain Relief 1% Gel
4. Possible side effects
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6. Contents of the pack and other information

1. What Amgesic Pain Relief 1% Gel is and what it is used for

Amgesic Pain Relief 1% Gel contains the active substance diclofenac sodium which belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). It is specially formulated for rubbing into the skin and is used to relieve pain and reduce inflammation and swelling in painful conditions affecting the joints and muscles. Amgesic Pain Relief 1% Gel can be used to treat:

- muscle and joint injuries (e.g. sprains, strains, bruises, sports injuries)
- tendonitis (e.g. tennis elbow)

2. What you need to know before you use Amgesic Pain Relief 1% Gel

DO NOT use Amgesic Pain Relief 1% Gel:

- if you are allergic to diclofenac or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic (hypersensitive) to acetylsalicylic acid (aspirin) or to other non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen. Symptoms of an allergic reaction to these medicines may include: asthma, wheezing or shortness of breath; skin rash or hives; swelling of the face or tongue; runny nose.
- **this medicine is not recommended for use in children under 14 years of age.**
- if you are in the last 3 months of your pregnancy (see also “Pregnancy and breast-feeding”).
- if you have kidney problems.

Warnings and precautions

- Do not apply the gel to skin that has (i) a rash or eczema (ii) cuts or open wounds. Stop the treatment if a skin rash develops after applying the product.
- Avoid applying on large areas of skin and over a prolonged period of time, unless under medical advice.
- Be careful when sunbathing or using sun lamps as your skin may be more sensitive to sunlight.

- If you have a stomach or duodenal ulcer (or a history of), tell your doctor or pharmacist before using the gel.
- If you have or have ever had asthma speak to your doctor or pharmacist before using the gel.
- 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 have been reported. 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. Amgesic Pain Relief 1% Gel should be discontinued at the first signs of rash, mucosal lesions or other manifestations of hypersensitivity.
- Do not apply the gel to mucous membranes (for example in the mouth). It cannot be ingested.

Other medicines and Amgesic Pain Relief 1% Gel

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines, including those obtained without a prescription. Do not use Amgesic Pain Relief 1% Gel if you are already taking diclofenac tablets or other pain/inflammation tablets (e.g. aspirin or ibuprofen). Anti-inflammatory medicines such as diclofenac may decrease the effectiveness of diuretics and other medicines for reducing high blood pressure. Diuretics are medicines that reduce the amount of fluid in the blood vessels, and this helps to lower your blood pressure. In some patients with impaired kidney function, for example dehydrated patients or elderly with impaired kidney function, use of Amgesic Pain Relief 1% Gel at the same time as diuretics may result in the worsening of the kidney function, with the possibility of acute kidney failure, which is usually reversible. The occurrence of these interactions should be considered, particularly if Amgesic Pain Relief 1% Gel is used on large areas of the skin for prolonged periods, in combination with diuretics and other blood pressure medicines. Since absorption of diclofenac through the skin is very low, such interactions are very unlikely.

Amgesic Pain Relief 1% Gel with food and drink

There are no known interactions of Amgesic Pain Relief 1% Gel with food and/or drinks.

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 taking this medicine.

Pregnancy

Do not use Amgesic Pain Relief 1% Gel if you are in the last 3 months of pregnancy. You should not use Amgesic Pain Relief 1% Gel 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 Amgesic Pain Relief 1% Gel can cause adverse effects in your unborn baby. It is not known if the same risk applies to Amgesic Pain Relief 1% Gel when it is used on the skin.

Breast-feeding

Amgesic Pain Relief 1% Gel should only be used under medical advice during breast-feeding as diclofenac passes into breast milk in small amounts. Amgesic Pain Relief 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

Amgesic Pain Relief 1% Gel does not affect the ability to drive or use machines.

Important information about some of the ingredients of Amgesic Pain Relief 1% Gel

Amgesic Pain Relief 1% Gel contains propylparaben (E216) and methylparaben (E218), which may cause allergic reactions, possibly delayed. Amgesic Pain Relief 1% Gel also contains propylene glycol which may cause skin irritation.

3. How to use Amgesic Pain Relief 1% Gel

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Use this medicine only on your skin. Do not use in your mouth. Be careful not to get the gel in your eyes. If this happens, rinse your eyes with clean water and tell your doctor. Check with your doctor, pharmacist or nurse if you are not sure.

Adults and children 14 years and over

The gel should be rubbed gently into the skin 3-4 times daily. Depending on the size of the affected site to be treated, an amount ranging in size from a 1 penny to a 2 pence piece (2 to 4 grams) of gel should be applied 3-4 times a day. **Do not apply more than 4 times in any 24 hour period. Allow at least 4 hours between applications.** The maximum daily dose is 16g. The maximum weekly dose is 112g.

After application, the hands should be washed unless they are the site being treated.

If symptoms do not improve by day 7, or if they worsen within the first 7 days, a consultation with a doctor is recommended. Consultation with a doctor is recommended if more than two major joints in the body are affected. Do not use for more than 7 days unless recommended by a doctor.

Do not rub the gel into cuts, open wounds or any other area where the skin is abnormal. After rubbing the gel into the skin, do not cover with bandages or plasters.

Wash your hands after rubbing in the gel, unless your hands are the site being treated.

This medicine is not recommended for use in children under 14 years of age.

If you use more Amgesic Pain Relief 1% Gel than you should

If you or a child accidentally swallows Amgesic Pain Relief 1% Gel, contact your doctor or accident and emergency department immediately.

If you forget to use Amgesic Pain Relief 1% Gel

If you miss your application at the correct time, apply it as soon as you remember then carry on as normal. Do not apply a double quantity to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. **Some rare and very rare side effects may be serious.**

You should immediately stop the treatment with Amgesic Pain Relief 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 in swallowing;
- wheezing, shortness of breath or feeling of tightness in the chest (asthma)
- swelling particularly of the face, lips, tongue or throat (angioedema)

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)
- asthma

Not known

- Burning sensation at the application site
- Dry skin

Prolonged use of Amgesic Pain Relief 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 Amgesic Pain Relief 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, discard any unused product after 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 Amgesic Pain Relief 1% Gel contains

The active substance is diclofenac sodium. Each gram of gel contains 10 mg diclofenac sodium, equivalent to 11.6 mg diclofenac diethylammonium. The other ingredients are: sodium hydroxide, hydroxyethyl cellulose, carbomers, propylene glycol, medium-chain triglycerides, propylhydroxybenzoate (E216), methyl-hydroxybenzoate (E218) and purified water.

What Amgesic Pain Relief 1% Gel looks like and contents of the pack

Amgesic Pain Relief 1% Gel is a white, smooth, homogeneous gel, with a slight characteristic odour, is packaged in aluminium tubes with a high density polyethylene cap containing 60 g or 100 g of gel, or aluminium tubes with a polypropylene cap containing 30 g or 50 g of gel. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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Manufacturer

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Amdeepcha

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