

## Package leaflet: Information for the user

### Diclofenac sodium 3% gel

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

#### **1. What Diclofenac sodium gel is and what it is used for**

Diclofenac sodium gel is a non-steroidal anti-inflammatory dermatological gel. Diclofenac sodium gel is applied to the skin to treat a skin problem known as actinic or solar keratosis that is caused by long-term extensive sun exposure.

#### **2. What you need to know before you use Diclofenac sodium gel**

##### **Do not use Diclofenac sodium gel**

- if you are allergic to diclofenac or any of the other ingredients of this medicine (listed in section 6).
- if you have ever experienced an allergic reaction such as skin rash (nettle rash), breathing problems (wheezing) or runny nose (allergic rhinitis) after taking aspirin or any other non-steroidal anti-inflammatory medicinal products.
- if you are in the last 3 months of pregnancy.

##### **Warnings and precautions**

Talk to your doctor or pharmacist before using Diclofenac sodium gel.

- The possibility of systemic adverse reactions following application of Diclofenac sodium gel cannot be excluded when the medicinal product is used on large areas of skin and for a prolonged period of time. Consult your doctor if you:
  - have, or have had in the past, a stomach ulcer or bleeding from the stomach,
  - have heart, liver or kidney problems,
  - have any type of bleeding disorder or bruise easily.

- Avoid direct sun exposure and the use of tanning salons when using Diclofenac sodium gel. If skin reactions occur, discontinue use of this medicinal product.
- Do not apply to wounds, infected skin or inflammation of skin.
- Do not allow Diclofenac sodium gel to come into contact with your eyes or the inside (mucosal lining) of your mouth or nose and do not swallow it. If Diclofenac sodium gel has accidentally been swallowed, consult a doctor immediately.
- Discontinue use of Diclofenac sodium gel and consult your doctor if you develop a wide-spread skin rash.
- After applying products containing diclofenac on the skin you can use a permeable (non-occlusive) bandage. Do not use an airtight occlusive dressing.

### **Children and adolescents**

Dosage recommendations and indications for the use of Diclofenac sodium gel have not been established for use in children and adolescents.

### **Other medicines and Diclofenac sodium gel**

Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use 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 using Diclofenac sodium gel. Do not use Diclofenac sodium gel if you are in the last 3 months of pregnancy. You should not use Diclofenac sodium 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 Diclofenac sodium can cause adverse effects in your unborn baby. It is not known if the same risk applies to Diclofenac sodium when it is used on the skin.

Consult your doctor if you are breast-feeding. Diclofenac sodium gel can be used with caution whilst breast-feeding but it must not be used on the breasts.

If you are pregnant, planning to have a baby, or breast-feeding, and your doctor considers treatment appropriate, Diclofenac sodium gel must not be applied to an area of the skin larger than a third of your body and must not be used for longer than three weeks.

Ask your doctor or pharmacist for advice before taking/using any medicine.

### **Driving and using machines**

No specific precautions are necessary.

### **Diclofenac sodium gel contains benzyl alcohol**

This medicine contains 15 mg benzyl alcohol in each gram of gel. Benzyl alcohol may cause allergic reactions and mild local irritation.

## **3. How to use Diclofenac sodium gel**

- Diclofenac sodium gel is not suitable for children.

- Always use Diclofenac sodium gel exactly as your doctor has told you. Check with your doctor if you are not sure.
- Pierce the aluminium membrane across the tube opening with the cap before use.
- Gently spread a small amount of gel onto the skin area to be treated. The amount of gel needed will vary depending on the size of the area to be treated. Usually 0.5 grams of gel (equivalent to about the size of a pea) will be enough for one area (5 cm x 5 cm). However, not more than 8 grams should be used per day.
- You can apply Diclofenac sodium gel twice daily unless your doctor tells you differently. You may notice a slight cooling effect when applying the gel onto your skin.
- The usual duration of treatment is 60 to 90 days. Maximum effect has been seen with treatment times closer to 90 days. Complete healing may not occur for up to a month after treatment has stopped.
- After applying the gel, the hands should be wiped on a paper towel and then washed, unless they are the area to be treated. The paper towel should be disposed of in the residual waste. This helps to significantly reduce diclofenac release into the waste water system (water pollutant).

#### **If you use more Diclofenac sodium gel than you should**

If the recommended dosage is significantly exceeded when applied to the skin, the gel should be removed again (e.g. with a paper towel, to be disposed of in the residual waste) and washed off with water.

#### **If you forget to use Diclofenac sodium gel**

Continue to apply as directed but do not apply twice as much to make up for the missed application.

#### **4. Possible side effects**

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

#### **If you have any of the following side effects, stop using Diclofenac sodium gel and contact your doctor as soon as possible:**

Skin rash (nettle rash); breathing problems (wheezing); swelling of the face; runny nose (allergic rhinitis). These symptoms indicate that you may be allergic to Diclofenac sodium gel.

If any of the following common side effects are severe or last for more than a few days, you should stop using Diclofenac sodium gel and contact your doctor: itching, skin rash, skin redness, inflammation, contact dermatitis, pain and blistering.

#### **Other common side effects:** (may affect up to 1 in 10 people)

Irritation or tingling at the site of treatment, conjunctivitis, allergy, a painful sensation when the skin is touched, pins and needles, muscle stiffness, inflammation of the skin, eczema, dry skin, swelling, skin rash (including scaling or blistering), sagging of the skin and skin ulcer.

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

Eye pain, weeping/dry eyes, abdominal pain, diarrhoea, feeling sick, hair loss, facial swelling, excessive bleeding or oily skin, a measles-like skin rash.

#### **Rare side effects:** (may affect up to 1 in 1,000 people)

Skin inflammation with large blisters

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

Bleeding from your stomach, kidney problems, breathing difficulties (asthma), all types of hypersensitivity reactions (including nettle rash, rapid swelling of the skin and mucous membranes), infected skin rash, skin sensitivity to sunlight.

Temporary hair discolouration at the application site has been reported. This is usually reversed after stopping treatment.

### **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 the Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://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 sodium 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 tube and carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

### **Shelf life once opened**

Once the tube is opened, Diclofenac sodium gel has a shelf life 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 sodium gel contains**

#### The active substance is:

diclofenac sodium

1 g gel contains 30 mg diclofenac sodium.

#### The other ingredients are:

sodium hyaluronate; macrogol 400; benzyl alcohol; purified water

### **What Diclofenac sodium gel looks like and contents of the pack**

Diclofenac sodium gel is a clear, transparent, colourless to yellowish gel and is supplied in aluminium tubes containing 10 g, 25 g, 26 g, 30 g, 50 g, 60 g, or 90 g.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

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