

Package leaflet: Information for the patient

Solaraze 3%, gel Diclofenac Sodium 3 % w/w

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

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2. What you need to know before you use Solaraze
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1. What Solaraze is and what it is used for

Solaraze contains the active substance diclofenac sodium and is a non-steroidal anti-inflammatory dermatological gel. When applied to the skin, Solaraze gel is used to treat a skin problem known as actinic or solar keratosis that is caused by long-term sun exposure.

2. What you need to know before you use Solaraze

Do not use Solaraze

- If you are allergic to diclofenac sodium or any of the other ingredients of this medicine (listed in section 6).
- If you have had an allergic reaction such as skin rash (nettle rash), breathing difficulties (wheezing) or runny nose (allergic rhinitis) after taking acetylsalicylic acid or any other non-steroidal anti-inflammatory agents.
- If you are in the final 3 months of your pregnancy.

Warnings and precautions

Talk to your doctor before using Solaraze.

- The possibility of systemic side effects from application of Solaraze cannot be excluded if the product is used on large areas of skin and over a prolonged period. Consult your doctor if:
 - you have, or have had in the past, a stomach ulcer or bleeding from the stomach.
 - you have heart, liver or kidney problems.
 - you have any type of bleeding disorder or bruise very easily.
- Avoid sun exposure, including tanning salons, when using Solaraze. If skin reactions occur, discontinue use.
- Do not apply to skin wounds, infected skin or dermatitis.

- Do not allow Solaraze to come into contact with your eyes or the inside of your nose or mouth and do not swallow it. If Solaraze has accidentally been swallowed, consult a doctor immediately.
- Discontinue Solaraze 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

Actinic keratosis is a condition not generally seen in children and adolescents and was not studied. Therefore, dosage recommendations and indications for the use of Solaraze have not been established for use in children and adolescents. No data are available.

Other medicines and Solaraze

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Pregnancy and breast-feeding

Talk to your doctor if you are, or could be pregnant. Solaraze should be used with caution during the first six months of pregnancy but **must not** be used during the last three months of pregnancy.

Consult your doctor if you are breastfeeding. Solaraze can be used whilst breastfeeding with caution but should not be used on the breasts.

If you are pregnant, trying to get pregnant, or breastfeeding, and your doctor considers treatment appropriate, Solaraze must not be applied to an area of the skin larger than about a third of your body and must not be used for longer than three weeks.

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

Driving and using machines

Solaraze has no influence on the ability to drive and use machines.

Solaraze contains benzyl alcohol

This medicine contains 10 mg benzyl alcohol in each gram. Benzyl alcohol may cause allergic reactions and mild local irritation.

3. How to use Solaraze

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

Solaraze is intended for cutaneous use.

Instructions for use

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- Pierce the aluminium membrane across the tube opening with the cap before using.
- Gently smooth a small amount of gel onto the skin over the area to be treated. The amount of gel needed will vary depending upon the size of the area to be treated. Usually 0.5 grams of gel (about the size of a pea) will be enough for one area (5 cm × 5 cm) but not more than 8 grams should be used per day.
- You can apply Solaraze twice daily unless your doctor tells you differently. You may notice a slight cooling effect when you smooth the gel onto your skin.

- The usual period of treatment is 60-90 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.
- Wash your hands after applying the gel, unless your hands are being treated.

If you use more Solaraze than you should

Remove the excess gel by washing with water.

If you forget to use Solaraze

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

If you have any of the following side effects, stop using Solaraze and contact your doctor as soon as possible:

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

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

Other common side effects: (occur in between 1 and 10 out of every 100 patients)

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

Uncommon side effects: (occur in between 1 and 10 out of every 1,000 patients)

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

Rare side effects: (occur in between 1 and 10 out of every 10,000 patients)

Dermatitis with large blisters.

Very rare side effects: (occur in fewer than 1 in 10,000 patients)

Bleeding from your stomach, problems with your kidneys, breathing difficulties (asthma), infected skin rash, skin sensitivity to sunlight.

Temporary hair discolouration at the application site has been reported. This is usually reversed on 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, see below:

Ireland

HPRA Pharmacovigilance

Website: www.hpra.ie

United Kingdom

Yellow Card Scheme, Website 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 Solaraze

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date (shown as 'EXP') which is stated on the tube and carton. The date refers to the last date of that month.

Do not store above 25 °C.

Shelf life after opening: 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 Solaraze contains

- The active substance is diclofenac sodium. Each gram of gel contains the equivalent of 30 mg diclofenac sodium.
- The other ingredients are sodium hyaluronate, benzyl alcohol, macrogol monomethyl ether 350 and purified water.

What Solaraze looks like and contents of the pack

Solaraze gel is a clear, transparent, colourless or pale yellow gel packed in tubes containing 25 grams, 50 grams, 60 grams, 90 grams or 100 grams of gel.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Almirall, S.A.
Ronda General Mitre, 151
08022 Barcelona, Spain

Manufacturer

Almirall Hermal GmbH
Scholtzstrasse 3
D-21465 Reinbek
Germany

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