

**PACKAGE LEAFLET: INFORMATION
FOR THE USER**

Solaraze[®] 3%, gel

Diclofenac Sodium 3% w/w

**Read all of this leaflet carefully before
you start using this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Solaraze is and what it is used for
2. Before you use Solaraze
3. How to use Solaraze
4. Possible side effects
5. How to store Solaraze
6. Further information

1. WHAT SOLARAZE IS AND WHAT IT IS USED FOR

Solaraze 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. BEFORE YOU USE SOLARAZE

Do not use Solaraze

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

Take special care with 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 type of bleeding disorder or bruise 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.

Pregnancy/Breastfeeding

Speak 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.

3. HOW TO USE SOLARAZE

- Solaraze is not suitable for children.
- Use the gel as directed by your doctor.

- 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 (5cm x 5cm) 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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Solaraze can have 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.

If any of the side effects becomes serious or you notice any side effects not mentioned in this leaflet please inform your doctor or pharmacist.

5. How to store Solaraze

Keep Solaraze out of the reach and sight of children.

Do not use after the expiry date on end of tube and after 'EXP' or 'scadenza' on the carton. The date refers to the last date of that month.

Do not store above 25° C.

Shelf life after opening: 6 months

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Solaraze contains

- Each gram of gel contains the equivalent of 30mg diclofenac sodium (the active substance).
- The gel also contains 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 or 50 grams of product.

Product procured from within the EU, repackaged and distributed by the parallel product authorisation holder

PCO Manufacturing, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath

Manufacturer

Almirall Hermal GmbH, Scholtzstrasse 3, D-21465 Reinbek, Germany.

Parallel Product Authorisation Number:

465/275/1

Solaraze is a registered trademark of ALMIRALL S.A., Spain

Date of leaflet preparation by PCO

Manufacturing: April 2014