Solaraze® 3% Gel
(diclofenac sodium)

PATIENT INFORMATION LEAFLET

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.
Your medicine will be referred to as Solaraze throughout the leaflet.

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 (nettles 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 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 widespread 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.

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 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 discoloration 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, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE SOLARAZE
Keep Solaraze out of the sight and reach of children.
Do not use after the expiry date 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.
If your gel becomes discoloured or shows any other signs of deterioration, please ask your doctor or pharmacist before using your medicine.
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 grams, 2 x 25 grams or 4 x 25 grams of product.

MANUFACTURER AND PRODUCT LICENCE HOLDER
Manufactured by Almirall Hermal GmbH, Scholtzstrasse 3, D-21465 Reinbek, Germany. Procured from within the EU by Product Licence holder Star Pharmaceuticals Ltd., 5 Sandridge Close, Harrow, Middessex, HA1 1XD. Repackaged by Servipharm Ltd.

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.

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Diclofenac sodium 3% w/w Gel 2850 29.04.16[3]

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- 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.
Your medicine will be referred to as Diclofenac sodium throughout the leaflet.

In this leaflet:
1. What Diclofenac sodium is and what it is used for
2. Before you use Diclofenac sodium
3. How to use Diclofenac sodium
4. Possible side effects
5. How to store Diclofenac sodium
6. Further information

1. WHAT DICLOFENAC SODIUM IS AND WHAT IT IS USED FOR

Diclofenac sodium is a non-steroidal anti-inflammatory dermatological gel. When applied to the skin, Diclofenac sodium 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 DICLOFENAC SODIUM

Do not use Diclofenac sodium
- If you are allergic to diclofenac or any of the ingredients in Diclofenac sodium.
- 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 Diclofenac sodium
- The possibility of systemic side effects from application of Diclofenac sodium 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 Diclofenac sodium. If skin reactions occur, discontinue use.
  - Do not apply to skin wounds, infected skin or dermatitis.
  - Do not allow Diclofenac sodium to come into contact with your eyes or the inside of your nose or mouth and do not swallow it. If Diclofenac sodium has accidentally been swallowed, consult a doctor immediately.
  - Discontinue Diclofenac sodium and consult your doctor if you develop a widespread 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. Diclofenac sodium 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. Diclofenac sodium 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, Diclofenac sodium 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 DICLOFENAC SODIUM

- Diclofenac sodium 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 use.
- 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 Diclofenac sodium 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 Diclofenac sodium than you should
  Remove the excess gel by washing with water.
- If you forget to use Diclofenac sodium
  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, Diclofenac sodium can have side effects although not everybody gets them.
- The possibility of systemic side effects from application of Diclofenac sodium cannot be excluded if the product is used on large areas of skin and over a prolonged period.
- If any of the following common side effects are severe or last for more than a few days you should stop using Diclofenac sodium 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.

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  Dermatitis with large blisters.

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

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5. HOW TO STORE DICLOFENAC SODIUM

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Do not store above 25°C.

Shelf life after opening: 6 months.
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