

SOLARAZE®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using SOLARAZE?

SOLARAZE contains the active ingredient diclofenac sodium. SOLARAZE is used to treat a skin condition known as actinic keratosis, also called solar keratosis.

For more information, see Section [1. Why am I using SOLARAZE?](#) in the full CMI.

2. What should I know before I use SOLARAZE?

Do not use if you have ever had an allergic reaction to SOLARAZE or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use SOLARAZE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with SOLARAZE and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use SOLARAZE?

- Use SOLARAZE twice daily unless your doctor tells you differently.
- The amount of gel needed will vary depending on the size of the area to be treated. Usually 0.5 g of gel (about the size of a pea) will be sufficient for one area. Do not use more than 8 g daily.
- Gently smooth a small amount of gel onto the skin over the area to be treated. You may notice a slight cooling effect when you smooth the gel onto your skin.

More instructions can be found in Section [4. How do I use SOLARAZE?](#) in the full CMI.

5. What should I know while using SOLARAZE?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist
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	<p>you visit that you are using SOLARAZE.</p> <ul style="list-style-type: none"> ● Call your doctor straight away if you become pregnant. ● If you are going to have surgery, tell the surgeon or anaesthetist that you are using this medicine. ● Keep all of your doctor's appointments so that your progress can be checked. ● Avoid sun exposure, including tanning salons. If skin reactions occur, discontinue use.
<p>Things you should not do</p>	<ul style="list-style-type: none"> ● Do not stop using this medicine unless your doctor tells you to. ● Do not use SOLARAZE if you are in the third trimester of pregnancy. ● 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.

	<ul style="list-style-type: none">• Do not use an airtight occlusive bandage.
Looking after your medicine	<ul style="list-style-type: none">• Keep SOLARAZE in a cool dry place where the temperature stays below 25°C. Do not freeze.

For more information, see Section [5. What should I know while using SOLARAZE?](#) in the full CMI.

6. Are there any side effects?

Common side effects include inflammation, irritation, pain, itching, tingling and blistering at the site of treatment, hypersensitivity or painful sensation when the skin is touched, pins and needles, contact dermatitis, eczema, dry skin, redness, swelling, rash, scaly rash, thickening of the skin, skin ulcer, raised scar, exfoliation, conjunctivitis.

Serious side effects include muscle pain, swelling of the body, swelling of the face, lips, mouth, throat or lymph nodes/glands, which may cause difficulty in swallowing or breathing, bleeding of the stomach (may have dark stools or blood in stools).

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

SOLARAZE

Active ingredient(s): *diclofenac sodium*

Consumer Medicine Information (CMI)

This leaflet provides important information about using SOLARAZE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using SOLARAZE.**

Where to find information in this leaflet:

- [1. Why am I using SOLARAZE?](#)
- [2. What should I know before I use SOLARAZE?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use SOLARAZE?](#)
- [5. What should I know while using SOLARAZE?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using SOLARAZE?

SOLARAZE contains the active ingredient diclofenac sodium. SOLARAZE belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs) which are used to relieve pain and inflammation.

SOLARAZE is used to treat a skin condition known as actinic keratosis, also called solar keratosis, that results in scaly or crusted patches of skin caused by too much sun exposure.

2. What should I know before I use SOLARAZE?

Warnings

Do not use SOLARAZE if:

- you are allergic to diclofenac, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you are allergic to aspirin or any other NSAID medicine.
- you are in the third trimester of pregnancy.
- the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- are allergic to any foods, preservatives, medicines or dyes.
- have any other medical conditions, in particular a stomach ulcer, or bleeding from the stomach; heart disease; liver disease; kidney disease; blood disorder; skin problems, such as skin wounds, infections or conditions, such as contact dermatitis and exfoliative dermatitis.

- have previously had any allergic reactions which may be fever, rash and/or swelling of the face, lips, mouth, throat or lymph nodes/glands, (which may cause difficulty in swallowing or breathing), shortness of breath or fainting.
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is not known whether SOLARAZE passes into breast milk. Your doctor will decide whether or not you should use SOLARAZE.

Like most NSAID medicines, SOLARAZE is not recommended for use during pregnancy. If there is a need to consider its use during the first or second trimester of pregnancy, your doctor will discuss with you the benefits and risks of using it. If you are pregnant or attempting to conceive, the dose of SOLARAZE should be applied to an area of the skin as small as possible (less than about a third of your body) and must not be used for longer than three weeks.

Do not use SOLARAZE if you are in the third trimester of pregnancy.

It may affect your developing baby if you use it during pregnancy.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

At the recommended dose of SOLARAZE, it is unlikely that it will interfere with other medicines.

4. How do I use SOLARAZE?

How much to use

- The amount of gel needed will vary depending on the size of the area to be treated. Usually 0.5 g of gel (about the size of a pea) will be sufficient for one area.
- Do not use more than 8 g daily.
- Follow the instructions provided and use SOLARAZE until your doctor tells you to stop.

When to use SOLARAZE

- Use SOLARAZE twice daily unless your doctor tells you differently.

- The usual treatment period 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.

How to use SOLARAZE

- 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. You may notice a slight cooling effect when you smooth the gel onto your skin.
- Wash your hands after applying the gel unless your hands are being treated.

SOLARAZE is for external use only.

If you forget to use SOLARAZE

If you forget to use SOLARAZE, continue to apply the next dose as directed.

Do not apply twice as much gel to make up for the missed application.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

If you use too much SOLARAZE

If you think that you have used too much SOLARAZE, remove the excess gel by washing with water.

If someone swallows SOLARAZE, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using SOLARAZE?

Things you should do

Call your doctor straight away if you become pregnant.

If you are going to have surgery, tell the surgeon or anaesthetist that you are using this medicine. It may affect other medicines used during surgery.

Keep all of your doctor's appointments so that your progress can be checked.

Avoid sun exposure, including tanning salons. If skin reactions occur, discontinue use.

After applying SOLARAZE to the skin, you can use a permeable (non-occlusive) bandage at the area.

Remind any doctor, dentist or pharmacist you visit that you are using SOLARAZE.

Things you should not do

- Do not apply to skin wounds, infected skin or dermatitis.
- Do not use an airtight occlusive bandage.
- Do not allow SOLARAZE to come into contact with your eyes, or the inside of your nose or mouth
- Do not ingest SOLARAZE.
- SOLARAZE is not suitable for children.
- Do not use SOLARAZE to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.

Looking after your medicine

- Keep SOLARAZE in a cool dry place where the temperature stays below 25°C. Do not freeze.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">● burning, dryness, redness, inflammation, irritation, pain, itching, rash, swelling, tingling, blistering or hair loss at the site of treatment● contact dermatitis, eczema, dry or red skin, itching● hypersensitivity or painful sensation when the skin is touched● pins and needles● rash, sometimes blistering or scaly● skin reaction to sunlight● skin ulcer	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> ● raised scar ● facial swelling ● conjunctivitis, eye pain or weeping/dry eyes ● hair loss ● pain in the abdomen, feeling sick (nausea), diarrhoea ● bleeding ● asthma 	

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> ● muscle pain ● swelling of the body ● swelling of the face, lips, mouth, or throat, which may cause difficulty in swallowing or breathing ● swelling of the lymph nodes/glands ● bleeding of the stomach (may have dark stools or blood in stools) 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What SOLARAZE contains

Active ingredient (main ingredient)	diclofenac sodium
Other ingredients (inactive ingredients)	sodium hyaluronate benzyl alcohol polyethylene glycol monomethyl ether

	purified water
Potential allergens	None

Do not use this medicine if you are allergic to any of these ingredients.

What SOLARAZE looks like

SOLARAZE is a clear, transparent, colourless to pale yellow gel in a 25 g tube (Aust R 116785).

Who distributes SOLARAZE

Mayne Pharma International Pty Ltd

1538 Main North Road

Salisbury South, SA 5106

solaraze.com.au

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