

SOLARAZE[®] 3%gel

Diclofenac sodium 3% w/w

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about SOLARAZE. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

This leaflet was last updated on the date at the end of this leaflet.

Speak to your pharmacist or doctor to obtain the most up to date information on this medicine.

You can also download the most up to date leaflet from www.menarini.com.au

All medicines have risks and benefits. Your doctor has weighed the risks of you using SOLARAZE against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What SOLARAZE is used for

Your medicine is used to treat the skin condition known as actinic or solar keratosis.

It contains the active ingredient diclofenac sodium. Diclofenac sodium belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

Before you use SOLARAZE

When you must not use it

Do not use SOLARAZE if you have an allergy to:

- any medicine containing diclofenac sodium
- any of the ingredients listed at the end of this leaflet.
- Aspirin or any other NSAID medicine.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin
- fainting

Do not take this medicine if you are in the third trimester of pregnancy.

After applying SOLARAZE to the skin, you can use a permeable (non-occlusive) bandage at the area. Do not use an airtight occlusive bandage.

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

Do not take this medicine after the expiry date printed on the pack or

if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- stomach ulcer, or bleeding from the stomach
- heart disease
- liver disease
- kidney disease
- blood disorder
- skin problems, such as skin wounds, infections or a condition called exfoliative dermatitis.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Like most NSAID medicines, SOLARAZE is not recommended for use during pregnancy. If there is a need to consider it during your 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 during the third trimester of pregnancy.

Tell your doctor if you are breast-feeding.

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

If you have not told your doctor about any of the above, tell them before you start using SOLARAZE.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get 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.

How to use SOLARAZE

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions in this leaflet, ask your doctor or pharmacist for help.

How to use it

- Pierce the aluminium membrane across the tube opening with the cap before using.
- Wash your hands after applying the gel unless your hands are being treated.
- Gently smooth a small amount of gel onto the skin over the area to be treated.

The amount of gel needed will vary upon the size of the area to be treated. Usually 0.5 grams of gel

(about the size of a pea) will be sufficient for one area.

Never swallow SOLARAZE.

When to use it

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.

How long to use it

Continue using your medicine for as long as your doctor tells you.

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.

If you forget to use it

If you forget to use SOLARAZE continue to apply 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 take your medicine, ask your pharmacist for some hints.

If you use too much (overdose)

If you use more SOLARAZE than you should, remove the excess gel by washing with water.

While you are using SOLARAZE

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking SOLARAZE.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

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.

Things you must not do

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.

SOLARAZE is not suitable for children.

Do not take 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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking SOLARAZE.

This medicine helps most people but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are mild and short lived.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you experience any of the following and they worry you:

- Inflammation, irritation, pain, tingling or blistering at the site of treatment.
- Conjunctivitis.
- Contact dermatitis.
- Eczema
- Hypersensitivity or painful sensation when the skin is touched. Pins and needles.
- Muscle pain.
- Itching.
- Dry or red skin.
- Swelling.
- Rash, sometimes blistering or scaly
- Skin swelling (hives)
- Spotting on the skin.
- Sagging of the skin.
- Skin reaction to sunlight.
- Skin ulcer
- Eye pain or weeping/dry eyes.
- Pain in the abdomen, feeling sick, diarrhoea.
- Hair loss.
- Facial swelling.
- Excessive bleeding
- Asthma

If any of the following happen, stop using SOLARAZE and tell your doctor immediately or go to Emergency at your nearest hospital:

- Swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Bleeding of the stomach.
- Problems with your kidneys.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using SOLARAZE

Storage

Keep SOLARAZE in a cool dry place where the temperature stays below 25°C.

Do not freeze it.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

SOLARAZE is a clear transparent colourless or light orange gel in a 25 g or 50 g tube.

Not all pack sizes may be available.

Ingredients

SOLARAZE contains 3% w/w of diclofenac sodium as the active ingredient.

Other ingredients are:

- Sodium hyaluronate,
- benzyl alcohol,
- macrogol monomethyl ether 350,
- purified water

Sponsor

SOLARAZE is supplied in Australia by:

A. Menarini Australia Pty. Ltd.,

Level 8, 67 Albert Ave,
Chatswood, NSW, 2067

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