

SOLARAZE(TM) 3% GEL

Diclofenac Sodium

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Solaraze.

It does not contain all available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risk of you using Solaraze against the benefit it is expected to have for you.

If you have any concerns about using this medicine, talk to your doctor or pharmacist.

Keep this leaflet with the medicine.

You may want to read it again.

What Solaraze is used for

The name of your medicine is Solaraze. It contains the active ingredient diclofenac sodium. Diclofenac sodium belongs to a group called non-steroidal anti-inflammatory drugs (NSAIDs).

Solaraze is used to manage the skin condition known as actinic or solar keratosis.

Before you use Solaraze

When you must not use it

Do not use Solaraze if:

- * You are allergic to diclofenac sodium or any of the inactive ingredients listed at the end of this leaflet.
- * You are allergic to Aspirin or any other NSAID medicine. Symptoms of an allergic reaction to these medicines may include: asthma, wheezing or shortness of breath, swelling of the face, lips or tongue, hives, itching or skin rash, fainting.
- * You are in the last trimester of pregnancy.
- * The tamper seal is broken.
- * The expiry date printed on the carton is passed.

If you are not sure whether you should start using Solaraze, contact your doctor.

Before you start to use it

Tell your doctor or pharmacist if:

- * You have any allergies to any other medicine or any other substances such as foods, preservatives or dyes.
- * You are pregnant or intend to become pregnant. Like most NSAID medicines, Solaraze is not recommended for use during pregnancy. If there is a need to consider Solaraze during your pregnancy, your doctor will

discuss with you the benefits and risks of using it. Solaraze should be not used during the third trimester of pregnancy. If you are pregnant, 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.

- * You are breast-feeding or intend to breast-feed. It is not known whether Solaraze passes into breast milk. Your doctor will decide whether or not you should use Solaraze.
- * You have, or have had, a stomach ulcer or bleeding from the stomach or if you have heart, liver or kidney disease or a blood disorder.
- * You have any problems with your skin such as skin wounds, infections or if you have a condition called exfoliative dermatitis.

If you have not told your doctor about any of the above, tell them before you use any Solaraze.

Taking other medicines

At the recommended dosages of Solaraze, interactions with other medicines are unlikely.

How to use Solaraze

Follow all directions given to you by your pharmacist or doctor 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.
- * 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.
- * Never swallow Solaraze.

How long to use it

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 use too much

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 become pregnant while using Solaraze, tell your doctor immediately.
- * If you are about to start taking any new medicine, tell your doctor and pharmacist that you are using Solaraze.
- * Tell all of the doctors, dentists and pharmacists that are treating you that you are using Solaraze.
- * If you are going to have surgery, tell your doctor you are using Solaraze.
- * 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 give Solaraze to anyone else, even if they have the same condition as you.
- * Do not use Solaraze to treat any other complaints unless your doctor tells you to.

Side effects

Like all medicines, Solaraze can cause some side effects. Sometimes they are serious, most of the time they are mild and temporary.

Do not be alarmed by this list of possible side effects. You may not experience any of them. Ask your pharmacist or doctor to answer any questions you may have.

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

Tell your doctor if you experience any of the following side effects and they worry you:

- * Inflammation, irritation, pain, tingling or blistering at the site of treatment.
- * Conjunctivitis.
- * Contact dermatitis.
- * 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.
- * Spotting on the skin.
- * Sagging of the skin.
- * Skin reaction to sunlight.
- * Eye pain or weeping/dry eyes.
- * Pain in the abdomen, feeling sick, diarrhoea.
- * Hair loss.
- * Facial swelling.

If any of the following happen, stop taking diclofenac sodium, and tell your doctor immediately, or go to accident and 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.

These are very serious side effects. You may need urgent medical attention or hospitalisation. All of these side effects are very rare.

After using Solaraze

Storage

Keep Solaraze in a cool and dry place where the temperature stays below 25 degrees C and out of the reach of children. Do not freeze.

Disposal

Return any unused or out of date medicine to your pharmacist.

Product description

What Solaraze looks like

Solaraze is a clear transparent colourless or pale yellow gel.

Active ingredient

Diclofenac sodium 3% w/w

Other ingredients

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

Distributed by

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