

FLAMAZINE™ Cream

silver sulfadiazine

Consumer Medicine Information

What is in this leaflet ?

This leaflet answers some common questions about FLAMAZINE. It does not contain all of the available information.

It does not take the place of talking to your doctor (or pharmacist).

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

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

Keep this leaflet with your medicine.

You may need to read it again.

What FLAMAZINE is used for

FLAMAZINE is a topical antibacterial cream with an active ingredient which belongs to the group of antibiotic medicines called sulfonamides.

FLAMAZINE is used to prevent infection in severe burns. Other types of wounds, such as pressure sores and leg ulcers, may also benefit from the application of FLAMAZINE cream.

- It is soothing when applied and has proven activity against a broad range of organisms including both Gram-positive and Gram-negative bacteria and some viruses and fungi.

Your doctor may have prescribed FLAMAZINE for another reason.

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

This medicine is available only with a doctor's prescription (except for Pharmacy-Only 50g tube in NZ).

Before you use FLAMAZINE

When you must not use it

Do not use FLAMAZINE if:

you have an allergy to:

- FLAMAZINE or any medicine within the Sulfonamide group or any of the ingredients in FLAMAZINE listed at the end of this leaflet.

Ask your doctor *or pharmacist* if you are not sure.

Do not give FLAMAZINE to premature infants or newborn infants in the first months of life. Sulfonamides may cause a life-threatening condition known as "*kernicterus*" (jaundice of the brain) in babies during the first months of life by interfering with normal metabolism.

Tampering and expiry date warnings:

Do not use FLAMAZINE if the tube or jar has been opened or shows signs of tampering before your first application.

Do not use FLAMAZINE if the expiry date (EXP) printed on the tube or jar has passed.

If you use this medicine after the expiry date has passed, it may not work effectively.

Before you start to use it

Tell your doctor if:

- 1. you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.**
- 2. you are pregnant or intend to become pregnant**

FLAMAZINE should not be used during the last month of pregnancy. Your doctor will discuss the risks and benefits of using FLAMAZINE when pregnant.

- 3. you are breast-feeding or intend to breast-feed**

Sulfonamides are excreted in the milk in small amounts and should be used with caution in breast-feeding mothers. Your doctor will discuss the risks and benefits of using FLAMAZINE when breastfeeding.

Do not apply FLAMAZINE to the breasts before breast feeding.

- 4. you know you are glucose-6-phosphate deficient**

- 5. you have or have had any other medical conditions, including:**

- **Low white blood cell count:** A fall in white blood cell count has been demonstrated very occasionally, but it is not thought to be associated with the treatment.

Nevertheless, regular blood counts are advisable if you are on long-term treatment.

- **Problems with your liver and / or kidney.**

FLAMAZINE should be used with caution in patients with

poor liver or kidney function. Reaction to the cream can sometimes cause worsening in these areas but the incidence is lower than with other sulfonamides.

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

Using other medicines

Tell your doctor or pharmacist if you are using other creams, ointments or lotions or taking any medicine. This includes any that you buy without a prescription from a pharmacy, supermarket or health food shop.

How to use FLAMAZINE

How much to use

One jar or tube of FLAMAZINE should be reserved for one person. If you are using jars, discard any remaining cream 24 hours after opening the jar. If you are using tubes, discard the product 7 days after opening.

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

These directions may differ from the information contained in this leaflet.

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

How to use it

FLAMAZINE should be applied by means of a sterile spatula or by hand, covered with a sterile glove, in a layer approximately 3-5 mm thick. One application at least every 24 hours is normally sufficient but the number of times a day to apply the cream will depend on your own individual needs. Where necessary reapply FLAMAZINE to any area

where it has been removed during activity.

It is important to apply FLAMAZINE exactly as your doctor or pharmacist has told you. If you use it less often than you should, it may not work as well and your skin problem may not improve. Using it more often than you should may not improve your skin problem any faster and may cause or increase side effects.

Apply FLAMAZINE at about the same time every day.

How long to use it

Treatment is continued until healing is progressing satisfactorily or the burn site is ready for skin grafting.

Your doctor or pharmacist will tell you how long to keep applying FLAMAZINE cream.

Do not use FLAMAZINE for longer than your doctor tells you.

If you use FLAMAZINE for longer than your doctor or pharmacist tells you, the chance of side effects may increase.

If you are not sure how long to use FLAMAZINE, talk to your doctor.

If you swallow it

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26 in Australia / 0800 POISON or 0800 764 766 in NZ), or go to casualty at your nearest hospital, if you think that you or anyone else may have swallowed FLAMAZINE. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep these telephone numbers handy.

While you are using FLAMAZINE

Things you must do

Tell all doctors and pharmacists who are treating you that you are using FLAMAZINE.

If you feel that FLAMAZINE is not helping your condition, tell your doctor (or pharmacist).

Tell your doctor if, for any reason, you have not used FLAMAZINE exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

If you become pregnant while using FLAMAZINE, tell your doctor.

Things you must not do

Do not use FLAMAZINE in or near the eyes.

Do not give FLAMAZINE to anyone else, even if they have similar problems to yours.

Things to be careful of

Do not use large amounts of FLAMAZINE for a long time.

If you use large amounts for a long time, the chance of absorption through the skin and the chance of side effects increases.

Ask your doctor or pharmacist if you are concerned about the length of time you have been using FLAMAZINE.

Side effects

Tell your doctor or pharmacist if you do not feel well while you are using FLAMAZINE.

FLAMAZINE helps most people with skin problems 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 not. You may need

medical treatment if you get some of the side effects.

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

Tell your doctor if you notice any of the following and they worry you:

- Nausea, vomiting and diarrhoea
- Skin rash, increasing pain, burning or itching.

These side effects are usually mild.

Tell your doctor immediately if you notice any of the following:

- Red, raised bumps on the face and scalp (*lupus erythematosus*)
- Problems with urine volume or colour (*Renal or hepatic toxicity*)
- Heart pain (*myocarditis*),
- Severe abdominal pain (pancreatitis)
- Inflammation of the blood vessels causing nodular swellings along length of vessel (vasculitis, including polyarteritis nodosa).
- Allergy-type reactions such as blistering or angry red rash.
- Skin discolouration.

These are serious side effects. You may need urgent medical attention.

Serious side effects are rare.

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

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

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using FLAMAZINE

Storage

Keep FLAMAZINE in a cool dry place away from light where the temperature stays below 25°C. Refrigeration is not normally needed but in temperatures in excess of 30°C some form of cooling is desirable. Do not store FLAMAZINE or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills.

Keep FLAMAZINE where young 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 using FLAMAZINE or it has passed its expiry date, ask your pharmacist what to do with any that is left over.

Product description

What it looks like

FLAMAZINE is a sterile white cream. The cream is a semisolid oil in water emulsion.

Ingredients

Active ingredients: Silver Sulfadiazine 1% (10 mg/g).

Inactive ingredients: Propylene Glycol, Polysorbate 60, Polysorbate 80, Cetyl Alcohol, Glyceryl Monostearate, Paraffin Liquid and Purified Water.

Supplier

FLAMAZINE is supplied in Australia by:

Smith & Nephew Pty. Ltd.
4 Drake Avenue,
Macquarie Park, NSW 2113

Phone: 02 9857 3999

Fax: 02 9857 3900

FLAMAZINE 50g Tube
(AUST R 159342)

FLAMAZINE 500g Jar
(AUST R 159338)

FLAMAZINE is supplied in New Zealand by:

Smith & Nephew Ltd.
621 Rosebank Road, Avondale,
Auckland 1026

Phone: 09 828 4059

Fax: 09 820 2868

FLAMAZINE 50g Tube

FLAMAZINE 500g Jar

Prepared May 2023

TMTrademark of Smith & Nephew