

## 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 Flamazine?

Flamazine contains the active ingredient silver sulfadiazine. Flamazine is used to prevent infection in severe burns. For more information, see Section [1. Why am I using Flamazine?](#) in the full CMI.

### 2. What should I know before I use Flamazine?

Do not use if you have ever had an allergic reaction to silver sulfadiazine 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, have any allergies to any other medicines or any other substances, are glucose-6-phosphate deficient, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section [2. What should I know before I use Flamazine?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Flamazine and affect how it works. For more information, see Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use Flamazine?

- 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.

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

### 5. What should I know while using Flamazine?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using Flamazine</li><li>• If you feel that Flamazine is not helping your condition, tell your doctor (or pharmacist)</li><li>• Tell your doctor if, for any reason, you have not used Flamazine exactly as prescribed</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not use Flamazine in or near the eyes</li><li>• Do not give Flamazine to anyone else, even if they have similar problems to yours</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful before you drive or use any machines or tools until you know how Flamazine affects you</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Tell your doctor if you drink alcohol</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep Flamazine in a cool dry place away from light where the temperature stays below 25°C</li><li>• Refrigeration is not normally needed but in temperatures in excess of 30°C some form of cooling is desirable</li></ul>

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

### 6. Are there any side effects?

Common less serious side effects include: nausea, vomiting, diarrhoea, skin rash, increasing pain, burning or itching. You may need urgent medical attention if you experience any of the following: red, raised bumps on the face and scalp, problems with urine volume or colour, heart pain, severe abdominal pain, inflammation of the blood vessels causing nodular swellings along length of vessel, allergy-type reactions such as blistering or angry red rash, skin discolouration, potentially life-threatening skin rashes. 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.

# Flamazine™

Active ingredient(s): *silver sulfadiazine*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Flamazine. **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 Flamazine.**

Where to find information in this leaflet:

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

## 1. Why am I using Flamazine?

**Flamazine contains the active ingredient silver sulfadiazine.** 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.**

## 2. What should I know before I use Flamazine?

### Warnings

**Do not use Flamazine if:**

- you are allergic to silver sulfadiazine, or any medicine within the Sulfonamide group, or any of the ingredients listed at the end of this leaflet.
- the tube or jar has been opened or shows signs of tampering before your first application
- 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.

- always check the ingredients to make sure you can use this medicine.
- 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.

### Check with your doctor if 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.
- take any medicines for any other condition
- have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes
- are glucose-6-phosphate deficient

Potentially life-threatening skin rashes (Stevens-Johnson Syndrome, toxic epidermal necrolysis) have been reported with the use of sulfadiazine, appearing initially as reddish target-like spots or circular patches often with central blisters on the trunk.

Additional signs to look for include ulcers in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes).

These potentially life-threatening skin rashes are often accompanied by flu-like symptoms. The rash may progress to widespread blistering or peeling of the skin.

The highest risk for occurrence of serious skin reactions is within the first weeks of treatment.

If you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis with the use of silver sulfadiazine, you must not be re-started on silver sulfadiazine at any time.

If you develop a rash or these skin symptoms, seek immediate advice from a doctor and tell him that you are taking this medicine.

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

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.**

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

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

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.

## 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.

**Some medicines may interfere with Flamazine and affect how it works.**

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Flamazine.**

## 4. How do I 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 the instructions provided and use Flamazine until your doctor tells you to stop.
- 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.

### When to use Flamazine

- Apply Flamazine at about the same time every day.
- 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.

### How long to use Flamazine

- 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 Flamazine

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.

### If you use too much Flamazine

If you think that you have used too much Flamazine, 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 Flamazine?

### Things you should do

**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.

**Call your doctor straight away if you:**

- become pregnant while using Flamazine

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

## Things you should 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.

## Driving or using machines

Be careful before you drive or use any machines or tools until you know how Flamazine affects you.

## Drinking alcohol

Tell your doctor if you drink alcohol.

## Looking after your medicine

- 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.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

## Keep it 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.

## When to discard your medicine (as relevant)

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.

## 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.

Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported. Although these reactions are very rare, if you notice any

signs and symptoms of serious skin reactions develop, immediately stop taking this medicine and seek urgent medical advice.

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
<b>Gut related:</b> <ul style="list-style-type: none"><li>• Nausea</li><li>• Vomiting</li><li>• Diarrhoea</li></ul> <b>Skin:</b> <ul style="list-style-type: none"><li>• Skin rash</li><li>• Increasing pain</li><li>• Burning or itching</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

## Serious side effects

Serious side effects	What to do
<b>Autoimmune related:</b> <ul style="list-style-type: none"><li>• Red, raised bumps on the face and scalp (lupus erythematosus)</li></ul> <b>Urinary:</b> <ul style="list-style-type: none"><li>• Problems with urine volume or colour (renal or hepatic toxicity)</li></ul> <b>Heart related:</b> <ul style="list-style-type: none"><li>• Heart pain (myocarditis)</li></ul> <b>Gastrointestinal:</b> <ul style="list-style-type: none"><li>• Severe abdominal pain (pancreatitis)</li></ul> <b>Vascular:</b> <ul style="list-style-type: none"><li>• Inflammation of the blood vessels causing nodular swellings along length of vessel (vasculitis, including polyarteritis nodosa)</li></ul> <b>Allergic reaction:</b> <ul style="list-style-type: none"><li>• Allergy-type reactions such as blistering or angry red rash</li></ul> <b>Skin:</b> <ul style="list-style-type: none"><li>• Skin discolouration</li><li>• Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis)</li></ul> <p>Some bacteria and fungal infections (e.g. thrush) may be resistant to the</p>	<b>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.</b>

effects of Flamazine and this could cause inflammation in burns wounds. Very occasionally an allergy can occur. If you experience redness and swelling you should consult your doctor.	
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**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](http://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 Flamazine contains**

Active ingredient (main ingredient)	Silver Sulfadiazine 1% (10 mg/g)
Other ingredients (inactive ingredients)	Propylene Glycol Polysorbate 60 Polysorbate 80 Cetyl Alcohol Glyceryl Monostearate Paraffin Liquid Purified Water
Potential allergens	n/a

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

**What Flamazine looks like**

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

FLAMAZINE 50g Tube (AUST R 159342)

FLAMAZINE 500g Jar (AUST R 159338)

**Who distributes Flamazine**

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 is supplied in New Zealand by:  
Smith & Nephew Ltd.  
621 Rosebank Road, Avondale,  
Auckland 1026  
Phone: 09 828 4059  
Fax: 09 820 2868

This leaflet was prepared in April 2024.  
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