

FLAMAZINE[◊]

Cream 1.0% w/w
Silver Sulfadiazine 10mg/g

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only.
- Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What FLAMAZINE Cream is and what it is used for.
2. What you need to know before you use FLAMAZINE Cream.
3. How to use FLAMAZINE Cream.
4. Possible side effects.
5. How to store FLAMAZINE Cream.
6. Contents of the pack and other information.

1. What FLAMAZINE Cream is and what it is used for

FLAMAZINE Cream contains silver sulfadiazine as the active ingredient. It works by killing bacteria or stopping their growth.

FLAMAZINE Cream is a sterile antibacterial cream used to:

- prevent or treat bacterial infections in burns.
- treat bacterial infections in leg ulcers or pressure sores for short periods of time.
- prevent bacterial infections in skin graft donor sites and large abrasions.
- treat finger-tip injuries where nail loss or partial loss of the end of the finger has occurred.

2. What you need to know before you use FLAMAZINE Cream

Do not use FLAMAZINE Cream

- if you are allergic to silver sulfadiazine or any of the ingredients such as cetyl alcohol and propylene glycol (*see section 6*)
- if you are allergic to sulphonamide medicines
- you are pregnant or breast-feeding

Do not use your medicine on premature babies or on newborn babies within the first few months of life.

Warnings and precautions

Consult your doctor, pharmacist or nurse before using your medicine if any of the following apply to you:

- if you suffer from kidney or liver problems.
- if you suffer from a deficiency of the enzyme known as glucose-6-phosphate dehydrogenase.
- if you are taking tablets prescribed by your doctor to control epilepsy or diabetes.

- if you are using a biological product to remove dead tissue from the leg ulcer or wound before using your medicine.
- 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.

Other medicines and FLAMAZINE Cream

The effects of using other medication may be altered where large areas of burns are treated. Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

FLAMAZINE Cream with food, drink and alcohol

There are no known effects of food, drink or alcohol on the use of FLAMAZINE Cream.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

There are no known effects.

FLAMAZINE Cream contains propylene glycol and cetyl alcohol

This medicine contains 7g propylene glycol in each 100g which is equivalent to 7% w/w. Propylene glycol may cause skin irritation. Cetyl alcohol may cause local skin reactions (e.g. contact dermatitis).

3. How to use FLAMAZINE Cream

It is unlikely that you will apply this medicine to yourself. A nurse or a doctor will normally apply the cream in which case the following directions apply:

- **Burns:**
 - The burn should first be cleaned.
 - Apply a 3-5 mm layer of your medicine to the burned area using a sterile glove or spatula.

- Cover the area with a non-stick dressing.
- Your medicine should be re-applied to the burn at least every day.
- **Hand Burns:**
 - Once your medicine has been applied as above, the hand may be enclosed in a plastic bag or glove, which is then closed at the wrist.
 - The hand and fingers should be moved as much as possible.
 - Your medicine should be re-applied to the burn when an excessive amount of fluid has built up in the bag and at least every day.

• Leg Ulcers & Pressure Sores:

- Fill the cavity of the ulcer or sore with medicine to a depth of 3-5mm and cover the wound with an absorbent pad.
- The doctor or nurse may tell you to apply a pressure bandage over the pad.
- Dressings should normally be changed at least every 1-2 days. Before re-applying your medicine, the ulcer or sore should be cleaned and the dead tissue removed.

• Finger-tip Injuries:

- Before applying the 3-5mm layer of your medicine, ensure that the injured finger has stopped bleeding.
- Cover the finger-tip with the finger of a plastic or non sterile surgical glove and fix in place with waterproof tape.
- Your medicine should be re-applied every 2-3 days.

If you use more FLAMAZINE Cream than you should

When used as directed an overdose is not likely. **Do not** use your medicine for a period longer than that prescribed by your doctor.

If you forget to use FLAMAZINE Cream

In the event of a missed treatment, contact your doctor as soon as possible.

Important: Always keep the contents of one tube or pot for the treatment of one person only.

4. Possible side effects

Like all medicines, FLAMAZINE Cream can cause side effects, although not everyone gets them. Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported (*see section 2*). 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. The following side effects may happen with this medicine:

Common (less than 1 per 10 but more than 1 per 100);

- Irritation.
- Rashes around the wound area (including eczema and contact dermatitis).
- Decreased white blood cells (leukopenia). This can lead to an increased risk of infection. This usually returns to normal within a few days; however a doctor will need to closely monitor you to ensure that the count returns to normal.

Rare (less than 1 per 1,000 but more than 1 per 10,000);

- Discolouration of the skin (due to absorption of silver over prolonged periods).

Very rare (less than 1 per 10,000);

- Kidney failure. Inform your doctor if you have difficulty in passing urine, passing a greater or smaller amount of urine than usual, or if you notice any blood or cloudiness in your urine. This may be a sign that your kidneys are not working properly.
- Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) (*see section 2*). Some bacteria and fungal infections (eg thrush) may be resistant to the effects of FLAMAZINE Cream 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 or nurse.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

5. How to store FLAMAZINE Cream

- Keep this medicine out of the sight and reach of children.
- Store your medicine below 25°C. Protect from the light.
- **Do not** use this medicine after the expiry date which is stated on the base of the tube or on the jar after EXP. The expiry date refers to the last day of that month.
- **Do not** use if you notice any visible signs of deterioration such as the cream being dark brown or black. Return it to your pharmacist and obtain fresh supplies.
- If you are using pots, discard any remaining cream 24 hours after opening.
- If you are using tubes, then you may use the cream for up to 7 days after opening.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What FLAMAZINE Cream contains

- The active substance is silver sulfadiazine. Each 100g of cream contains 1g of silver sulfadiazine.
- The other ingredients are polypropylene glycol, glycerol monostearate, cetyl alcohol, liquid paraffin, propylene glycol and purified water.

What FLAMAZINE Cream looks like and the contents of the pack

FLAMAZINE Cream is a white to off-white, sterile cream.

It is available in tubes containing 20g and 50g and pots containing 250g and 500g.

Marketing Authorisation Holder:

Smith & Nephew Pharmaceuticals Ltd,
101 Hessle Road, Hull HU3 2BN, England.
Marketing Authorisation (PL 13374/0006).

Manufacturer:

Recipharm Parets S.L.U.,
C/ Ramón y Cajal, 2, Parets del Vallés,
08150 Barcelona, Spain

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