

Package leaflet: Information for the user

FLAMAZINE Cream 1.0% w/w silver sulfadiazine

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.
- treat finger-tip injuries where nail loss or partial loss of the ends of the finger 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
- if 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, liver or breathing problems
- if you suffer from a deficiency of the enzyme known as glucose-6-phosphate dehydrogenase
- Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings, etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.
- 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 tablets to control epilepsy or diabetes and 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, Leg Ulcers & Pressure Sores:

- A layer of approximately 3 to 5mm thick should be applied to the affected area using a sterile glove or spatula. The area should then be covered by an absorbent gauze dressing and support bandage where necessary.

For burns treatment FLAMAZINE Cream should be applied at least every 24 hours.

For the treatment of leg ulcers and pressure sores FLAMAZINE Cream should be applied at least 3 times per week.

In all instances, following the application of FLAMAZINE Cream, the area should be covered with a new dressing.

- On occasions it may be necessary for the unhealthy tissue to be removed by your treating doctor or nurse (debridement).
- Care should be taken to avoid placing FLAMAZINE Cream on non-ulcerated areas.

• 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.
- Dressings should be changed 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 information

Always keep the contents of one tube or jar for the treatment of one person only.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Using FLAMAZINE Cream sometimes causes wound discoloration, (black or grey colour) this colour change is not a cause for concern. Sometimes bad burns can develop a dark/black crust over the wound (eschar) and this may last longer when using FLAMAZINE Cream.

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 other side effects may happen with this medicine:

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

- Irritation, burning sensation or itching.
- 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 HPRC Pharmacovigilance; Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store FLAMAZINE Cream

- Keep this medicine out of the sight and reach of children.
- Store your medicine below 25°C. Store in the original container. 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.
- 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 polysorbates, glycerol monostearate, cetyl alcohol, liquid paraffin, propylene glycol and purified water.

What FLAMAZINE Cream looks like and contents of the pack

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

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

Marketing Authorisation Holder and Manufacturer

Smith & Nephew GmbH, Friesenweg 30,
22763 Hamburg, Germany.
(PA 22696/002/001).

Manufacturer:

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

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- treat finger-tip injuries where nail loss or partial loss of the ends of the finger 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
- if 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, liver or breathing problems
- if you suffer from a deficiency of the enzyme known as glucose-6-phosphate dehydrogenase
- Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings, etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.
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- 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 tablets to control epilepsy or diabetes and 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).

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• Burns, Leg Ulcers & Pressure Sores:

- A layer of approximately 3 to 5mm thick should be applied to the affected area using a sterile glove or spatula. The area should then be covered by an absorbent gauze dressing and support bandage where necessary.
For burns treatment FLAMAZINE Cream should be applied at least every 24 hours.
For the treatment of leg ulcers and pressure sores FLAMAZINE Cream should be applied at least 3 times per week.
In all instances, following the application of FLAMAZINE Cream, the area should be covered with a new dressing.
- On occasions it may be necessary for the unhealthy tissue to be removed by your treating doctor or nurse (debridement).
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- 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.
- Dressings should be changed 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 information

Always keep the contents of one tube or jar for the treatment of one person only.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Using FLAMAZINE Cream sometimes causes wound discoloration, (black or grey colour) this colour change is not a cause for concern. Sometimes bad burns can develop a dark/black crust over the wound (eschar) and this may last longer when using FLAMAZINE Cream.

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 other side effects may happen with this medicine:

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

- Irritation, burning sensation or itching.
- 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);

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