

SILVERDERM CREAM

Silver Sulfadiazine (1g/100g)

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What Silverderm is used for

Silverderm is used to prevent and treat wound sepsis in patients with second and third-degree burns.

How Silverderm works

Silver sulfadiazine has broad antimicrobial activity against Gram-positive and Gram-negative bacteria. It works by killing bacteria or stopping their growth. This helps reduce or prevent infections. The time taken for the medicine to work will vary by wound type.

Before you use Silverderm

- When you must not use it

- Hypersensitive to silver sulfadiazine, or any other sulfonamides or any of the other ingredients listed at the end of this leaflet.
- Pregnant women approaching or at term.
- Premature infants.
- Newborn infants during the first 2 months of life.

- Before you start to use it

Please tell your doctor if you have:

- low white blood cell count;
- kidney or liver problem;
- extensive burns;
- glucose-6-phosphate dehydrogenase (G6PD) deficiency.

Absorption of propylene glycol which is contained in **Silverderm** may interfere with some laboratory test results.

If you are not sure whether you should start taking this product, consult your doctor.

- Taking other medicines

Tell your doctor or pharmacist about all the medicines you take, including supplements and traditional medicines.

The following may interact with **Silverderm**:

- enzymatic debriding agents (remove dead tissue from wounds)
- oral hypoglycaemic agents (for treatment of type 2 diabetes)
- phenytoin (prevent seizures)
- cimetidine (used for heartburn and ulcers).

- Pregnancy and lactation

Silverderm should not be used during the last month of pregnancy.

Sulfonamides are excreted in the milk in small amounts and should be used with caution in breastfeeding mothers.

Your doctor will discuss the risks and benefits of using **Silverderm** when pregnant or breastfeeding.

How to use Silverderm

- How much to use

The cream should be applied once to twice daily to a thickness of approximately 1/16 inch on the burn areas.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Treatment should be continued until satisfactory healing has occurred, or until the burn site is ready for grafting.

- If you forget to use it

If you miss an application, apply it as soon as possible. Do not use a double dose to make up for a missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this

medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

- Always use **Silverderm** exactly according to the instructions given to you by your doctor or pharmacists. Check with your doctor or pharmacist if you are unsure.
- Tell your doctor or pharmacist immediately if you notice any side effects, or if the side effects get serious or anything else that make you feel unwell.
- If you become pregnant, or plan on becoming pregnant while using **Silverderm**, tell your doctor immediately.
- If you are about to be started on a new medicine, remind your doctor and pharmacist that you are using **Silverderm**.

Silverderm contains chlorhexidine. Inform your healthcare provider if you have a known allergy to chlorhexidine. Stop using this product and seek immediate medical assistance if you experience rash, itching, swelling, breathing difficulties, light-headedness or rapid heartbeat.

- Things you must not do

Do not use **Silverderm** after the expiry date which is stated on the carton and tube.

- Things to be careful of

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

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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 restarted 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.

Side effects

Like many medicines, **Silverderm** may cause side effects in some people but not everyone will exhibit the same symptoms.

The following side effects may happen with this medicine:

Common:

- 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:

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

Very rare:

- Kidney failure. Inform your doctor if you have difficulty in passing urine, passing a greater or smaller amount of urine than usual, 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)

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website nppra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Silverderm

Storage

Store below 30 °C in a well-closed container.

Protect from heat and direct light.

For external use only.

Keep out of reach of children.

- Disposal

If your doctors tell you to stop taking **Silverderm** or the expiry date has passed, ask your pharmacist the proper way to dispose the remaining products.

Product Description

- What it looks like

Silverderm is a white cream.

- Ingredients

- Active ingredient

Silver sulfadiazine 1g/100g

- Inactive ingredients

Liquid paraffin, chlorhexidine gluconate solution 20%, zalibra 6888 (colour perfume), lanolin anhydrous, cetyl alcohol, carbomer 940, polysorbate 60, triethanolamine, propylene glycol, purified water.

- MAL Number

MAL20021379AZ

Manufacturer

T.O. CHEMICALS (1979) Ltd.,
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Product Registration Holder

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