SILVERDERM CREAM®

Silver Sulphadiazine (1g/100g)

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What Silverderm Cream is used for

Silverderm Cream is used:

- To prevent and treat infection in burn wounds
- As an aid to the short-term treatment in other skin conditions, such as leg ulcers
- As an aid to prevent infection in skin grafting.

How Silverderm Cream works

Silver sulphadiazine has broad antimicrobial activity against Gram-positive and Gram-negative bacteria. It works by killing bacteria or stopping their growth.

Before you use Silverderm Cream

- When you must not use it
- Hypersensitive to silver sulphadiazine, other sulphonamides or any of the other ingredients in the preparation such as cetyl alcohol and propylene glycol.
- 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 kidney or liver problem
- If you have extensive burns
- If you have glucose-6-phosphate dehydrogenase (G6PD) deficiency

Absorption of propylene glycol which is contained in Silverderm Cream 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

As the silver content of silver sulphadiazine may inactivate topical proteolytic enzymes and debriding agents (a type of medicine used externally to clean and treat wounds), their concomitant use may be inappropriate.

The effects of oral hypoglycaemic agents (anti-diabetic medication) and phenytoin (anticonvulsant medication) may be potentiated when 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 such as supplements or traditional medicines.

- Pregnancy and lactation

There are no adequate and controlled study being done in pregnant women, therefore the cream should be used during pregnancy only if clearly needed. Silver sulphadiazine should also be used with caution in nursing women.

Ask your doctor or pharmacist before taking or using any medicines.

How to use Silverderm Cream

- How much to use

Silverderm Cream is applied topically to cleansed burned/affected areas once or twice daily approximately 1.5mm thick, using a sterile-gloved hand or spatula. Dressing is usually not required but it can be used.

- When to use it

It should be applied to the burn wound/affected area as long as there is a possibility of infection or prescribed by the doctor. Whenever necessary, the cream should be re-applied to any areas from which it has been removed.

- 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)

There is little experience of overdosage with Silverderm Cream but if accumulation of sulphadiazine occurs, discontinuance of this cream should be considered.

For people who are on long-term/high dose therapy or people with impaired kidney function, it may be necessary to continuously monitor the possibility of crystal found in the urine.

While you are using it

- Things you must do
- Always use Silverderm Cream 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 gets serious or anything else that make you feel unwell.
- If you become pregnant, or plan on becoming pregnant while using Silverderm Cream, 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 Cream.

- Things you must not do

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

- Things to be careful of

Be careful while driving or operating machinery until you know how Silverderm Cream affects you.

Side effects

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

Tell your doctor if you have any of these symptoms:

• Burning, skin photosensitivity (sun allergy), itching (pruritus), skin rash, browngrey skin discolouration, blood disorders, skin and allergic reaction including Stevens-Johnson syndrome.

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 calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers -> Reporting)

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Storage and Disposal of Silverderm

Cream

Storage

Store between 25 and 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 Cream or the expiry date has passed, ask your pharmacist the proper way to dispose the remaining products.

Product Description

- What it looks like

Silverderm Cream is a white cream packed in an aluminium tube of 25g and 50g.

- Ingredients
- Active ingredient Silver sulphadiazine 1g/100g
- Inactive ingredients Liquid paraffin, chlorhexidine gluconate solution 20%, zalibra 6888, lanolin anhydrous, cetyl alcohol, carbomer 940, polysorbate 60, triethanolamine, propylene glycol, purified water.

- <u>MAL Number</u> MAL20021379AZ

Manufacturer

T.O.Chemicals (1979) Ltd., 280 Soi Sabaijai, Suthisarn Road, Bangkok 10320, Thailand.

Product Registration Holder

IMEKS Pharma Sdn. Bhd. No. 5 & 9, Jalan Udang Harimau 2, Medan Niaga Kepong, 51200 Kuala Lumpur, Malaysia.