SILFAZINE CREAM

Silver Sulphadiazine (1% w/w)

What is in this leaflet

- 1. What Silfazine Cream is used for
- 2. How Silfazine Cream works
- 3. Before you use Silfazine Cream
- 4. How to Silfazine Cream
- 5. While you are using it
- 6. Side effects
- 7. Storage and disposal of Silfazine Cream
- 8. Product description
- 9. Manufacturer and Product Registration Holder

10.Date of revision

What Silfazine Cream is used for

It is used as an adjunct for the prevention and treatment of wound sepsis(the presence of bacteria in the wound) in people with second and third-degree burns.

How Silfazine Cream works

The active ingredient in the medicine is Silver sulphadiazine. It has broad antimicrobial activity against gram-positive and gram-negative bacteria, yeasts and fungi. Silver sulphadiazine acts only on the cell membrane and cell wall to produce its substance to kill the bacteria.

Before you use Silfazine Cream

- When you must not use it

Do not use Silfazine Cream if:

- you are exhibited hypersensitivity to silver sulphadiazine or any other sulphonamide medicines or other ingredients listed at the end of this leaflet.
- you are pregnant
- your child is premature infants or newborn infants during the first month of life because sulfonamide therapy is known to increase the possibility of kernicterus (brain damage due to high level of bilirubin).

- Before you start to use it

Tell your doctor if you have any of the following:

- liver or kidney impairment
- inherited enzyme deficiency known as glucose-6-phosphate dehydrogenase deficiency

- Taking other medicines

Topical enzyme preparations that contain collagenase or papain (used as debriding agent) may be inactivated by the silver content of silver sulphadiazine if use concomitantly. Fatalities associated with usage of medicines such as sulphonamides and trimethoprim, either alone or in combination, have occured due to severe skin

reaction, including Steven-Johnson syndrome, toxic epidermal necrolysis and other reactions. The medicine should be discontinued at the first appearance of skin rash or any sign of adverse reaction.

How to use Silfazine Cream

- How much to use

Topical application.

The cream should be applied once to twice daily to a thickness of approximately 1/16 inch on the burn areas. It should be continue until satisfactory healing has ocurred or until the burn site is ready for grafting.

- When to use it

Use Silfazine Cream when needed and according to doctor prescription.

- How long to use it

It is important to take Silfazine Cream as long as your doctor prescribes.

- If you forget to use it

Do not take extra dose to make up for a missed dose. Just take your next dose at usual time.

- 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

Take Silfazine Cream exactly as your doctor has told you.

- Things you must not do

Do not share your medicines with others even if they have the same problem as you.

- Things to be careful of

If your experience any side effects, consult your doctor or pharmacist for advice.

Side Effects

Like all medicines, Silfazine Cream can cause side effects, although not everybody gets them. About 2.5% of people treated with silver sulphadiazine, the separation of the dark scab or falling away of dead skin may be delayed and fungal invasion of the wound

may occur. Since significant quantities of silver sulphadiazine are absorbed, it possible that any of adverse reactions attributable that to sulfonamides may occurs. Local reactions such as burning, itching and skin rash may occur. A reduction in the number of white cells in the blood may also occur.

Any other effects not listed above may also occur in some people. Please refer to your doctor or pharmacist if you experience any other symptoms while taking this medication.

You may report any side effect or adverse drug reaction directly to the National Centre for Adverse Drug Reaction Monitoring by calling 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers→Reporting).

Storage and disposal of Silfazine Cream

- Storage

Store at temperature 25 °C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like White, soft, smooth cream

- Ingredient(s)

- Active Ingredient Silver sulphadiazine

- Inactive Ingredients
- Liquid Paraffin
- Sodium Hydroxide 0.1m
- Methyl Paraben
- Sodium Lauryl Sulphate
- Propylene Glycol
- Cetomacrogol 1000
- White Soft Paraffin
- Deionised Water
- Cetostearyl Alcohol

<u>- MAL number</u> MAL19921154AZ

Manufacturer

Sunward Pharmaceutical Sdn. Bhd. No. 9,11 & 17, Jalan Kempas 4, Taman Perindustrian Tampoi Indah, 81200 Johor Bahru, Johor, Malaysia.

Product Registration Holder Sunward Pharmaceutical Sdn. Bhd. No. 9,11 & 17, Jalan Kempas 4, Taman Perindustrian Tampoi Indah, 81200 Johor Bahru, Johor, Malaysia.

Date of revision

26/10/2015

Serial Number BPFK(R4/1)211015/00378