PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Silverol® Cream

Skin cream

Composition

Silver Sulfadiazine 1%
in a water-soluble base.

For information regarding inactive ingredients and allergens in the medicine, see "Important information about some of the ingredients of the medicine" in section 2 and "Additional information" in section 6.

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for your treatment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. What is the medicine intended for?

A topical antimicrobial preparation for treatment of burns, infected pressure ulcers and infected leg ulcers.

Therapeutic class: antibacterial of the sulfonamides group.

2. Before using the medicine

Do not use this medicine:

- If you are sensitive (allergic) to the active ingredient, silver sulfadiazine, or to any of the other ingredients this medicine contains, such as cetostearyl alcohol or propylene glycol (see section 6 "Additional information")
- If you are pregnant or breastfeeding
- In premature or newborn infants during the first few months of their lives

Special warnings regarding the use of the medicine

Before treatment with Silverol Cream, inform the doctor, pharmacist or nurse if:

- You know that you are allergic to treatment with sulfonamides
- You are suffering from kidney or liver problems
- You have glucose-6-phosphate dehydrogenase (G6PD) deficiency
- You are taking medicines prescribed by your doctor for treatment of epilepsy or diabetes
- You are using a biological medicine for the removal of dead tissue from a leg ulcer or a sore

Drug-drug interactions

If you are taking or have recently taken other medicines, including non-prescription medicines and food supplements, tell the doctor or the pharmacist.

The effects of other medicines may be altered when extensive burn areas are being treated.

Use of the medicine and food

There are no known effects of food or drinks on the use of Silverol Cream.

Use of the medicine and alcohol consumption

There are no known effects of alcohol on the use of Silverol Cream.

Pregnancy and breastfeeding

The medicine must not be used if you are pregnant, planning to become pregnant or are breastfeeding.

Consult with the doctor or pharmacist before using any medicine.

Driving and operating machinery

No known effects.

Important information about some of the ingredients of the medicine

The medicine contains cetostearyl alcohol, which may cause local skin reactions (such as contact dermatitis).

This medicine contains 7 grams of propylene glycol in every 100 grams of cream. Propylene glycol may irritate the skin. Because this medicine contains propylene glycol, it should not be used on open wounds or extensive areas of broken or damaged skin (such as burns) without consulting a doctor or a pharmacist.

3. How should you use the medicine?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the medicine.

The dosage and treatment regimen will be determined only by the doctor. The generally accepted dosage is:

According to the doctor's instructions only.

Do not exceed the recommended dose.

How to use the medicine

Sterile measures should be taken when applying Silverol Cream and it should be applied directly onto the burn wounds after they have been thoroughly cleansed. The cream should be applied in a layer 3-5 mm thick over the entire area of the wound, according to the doctor's instructions. The infected area must be covered with cream at all times. If for any reason the cream is rubbed off, apply a new layer.

An individual tube should be used for each patient.

The tube should only be opened right before use.

Any cream remaining upon completion of the treatment should be discarded. Consult the pharmacist about the best way to do that.

Do not swallow. For external use only.

If you accidentally used a larger amount

If you used an overdose or if a child swallowed this medicine by mistake, go to the doctor or a hospital emergency room immediately and take the package of the medicine with you.

Follow the treatment as recommended by the doctor.

Do not take medicines in the dark! Check the label and the dose <u>every time</u> you take the medicine. Wear glasses if you need them.

If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, using Silverol cream may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Common side effects (occur in less than 1 of 10 users but in more than 1 of 100 users):

- Irritation
- Rash around the wound (including eczema and contact dermatitis).
- Decrease in the number of white blood cells (leukopenia), which may lead to an increased risk for infection. The values usually return to their normal range within a few days, but the doctor will need to monitor them closely to ensure that the count returns to normal.

Rare side effects (occur in less than 1 of 1,000 users but in more than 1 of 10,000 users):

- Skin discoloration (due to absorption of silver for prolonged periods [silver comes from the composition of the active ingredient – silver sulfadiazine]).

Very rare side effects (occur in less than 1 out of 10,000 users):

- Renal failure. Inform the doctor if you have difficulty urinating, if you pass more or less urine than usual, or if you notice blood or cloudiness in the urine. This may be a sign that the kidneys do not function properly.

Other side effects:

Hypersensitivity to sunlight

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.

<u>Reporting side effects</u>

Side effects may be reported to the Ministry of Health by clicking on the link "report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- **Store this medicine in a dark place below 25°C.**
- **The medicine may be used up to 12 months after first opening, but not after the expiry date.**
- Do not use the cream if you notice a change in the cream's appearance, such as a noticeable discoloration.

6. Additional information

In addition to the active ingredient, the medicine also contains:

Mineral oil, Propylene glycol, Glycerol monostearate, Cetostearyl alcohol, Glyceryl monostearate self-emulsifying, Polysorbate 60, Polysorbate 80, Methylparaben, Purified water

What does the medicine look like and what are the contents of the package

Silverol Cream is a white to slightly gray-white or pinkish-white, smooth glossy cream. Each package contains a tube containing 50 grams of cream.

Name and address of marketing authorization holder and manufacturer

Teva Israel Ltd.
124 Dvora HaNevi'a St., Tel Aviv 6944020

Registration number of the medicine in the national drug registry of the Ministry of Health:

020-56-20515

The leaflet was revised in May 2022 in accordance with the Ministry of Health guidelines.

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