

PACKAGE LEAFLET: INFORMATION FOR THE USER

Dermazin

1% Cream

SILVER SULFADIAZINE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking 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 or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What DERMAZIN is and what it is used for
2. Before you take DERMAZIN
3. How to use DERMAZIN
4. Possible side effects
5. How to store DERMAZIN
6. Further information

1. WHAT DERMAZIN IS AND WHAT IT IS USED FOR

Dermazin 10 mg / g cream is a topical medication containing silver sulfadiazine, which as the active ingredient, is used for the prevention and the treatment of inflammation (infection) in burns and other skin injuries (decubital wounds, varicose problems, scratches, minor injuries, cuts and other clean wounds, and wounds that develop during transplantation of one`s own skin.

Silver sulfadiazine disintegrates in the burn wound, thereby causing a slow and sustained release of silver ions. Silver ions bind to bacterial desoxyribonucleic acid, thus inhibiting the growth and multiplication of bacterial cells without affecting the cells of the skin and subcutaneous tissue.

Dermazin cream has a broad antibacterial spectrum, including nearly all micro-organisms that can lead to inflammation (infection) burns and other injuries. Dermazin penetrates into the necrotic tissue and exudates. This effect is very important since systemic antibiotics are not effective against the bacterial flora of the burn necrosis which is excluded from the blood flow.

2. BEFORE YOU TAKE DERMAZIN

Do not take DERMAZIN

- If you are allergic (hypersensitive) to sulfadiazine and / or any other ingredient of this product (listed in section 6).
- during pregnancy (especially in the prenatal period) (see section Pregnancy and breastfeeding)
- in preterm infants and newborns during the first 2 months of life, because it may cause jaundice (kernicterus)
- Dermazin cream contains peanut oil. People who are allergic to peanut oil or soybean should not use this medicine.

Tell your doctor or pharmacist:

Caution is required in the presence of hypersensitivity to sulfonamides because of possible allergic reactions; in patients with inborn G-6-PD deficiency as hemolysis may occur after the application of the cream to the large body surface area; as well as in the presence of hepatic and renal dysfunction.

During treatment with silver sulfadiazine there were reported the life-threatening reactions on the skin (Stevens-Johnson syndrome, toxic epidermal necrolysis), with the formation of a reddish rounded flat rash or roundish stain involving blistering on the body. Further symptoms include the appearance of ulcer (ulcers or lesions) in the mouth, throat, nose, genitals and conjunctiva (red and swollen eyes).

All these indicated life-threatening skin rashes symptoms are often accompanied with symptoms similar to flu. The rash can lead to heavy rusting and flaking of the skin. The risk of severe skin reactions is highest during the first few weeks of treatment. If you experience skin rash or mentioned symptoms on the skin, please seek immediate medical advice and tell your doctor about using this medicine.

As with other local antimicrobials, you may experience superinfection (re-inflammation after treatment of the same person) after treatment with silver sulfadiazine.

Make sure the cream does not get into your eyes!

When treatment with Dermazin cream involves prolonged administration or large burn surfaces, the white blood cell count should be monitored, as leukopenia may occur.

Gray discoloration of the skin may occur after exposure to the sun.

It is necessary to immediately contact your doctor if you experience yellowing of the skin or mucous membranes (symptoms of a possible lack of the enzyme glucose-6-phosphate dehydrogenase).

Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Concomitant use with Dermazinom can influence the effect of the following medicines or group of preparations:

- local proteolytic enzymes: silver can prevent the action of so called enzymes for topical administration (enzymes required for the degradation of proteins) if they are used with silver sulfadiazine
- cimetidine: when used simultaneously with Dermazin cream (cimetidine-medicine that is used for reducing gastric acid secretion and the treatment ulcer of stomach and duodenum) there were frequent reports of a reduced number of white blood cells
- in the treatment of extensive burns (if silver sulfadiazine is used in larger quantities) there may be changes in the effect of orally applied medicines.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Do not use Dermazin cream in a state of advanced pregnancy, because the newborn may experience jaundice (kernicterus). If sulfonamides are used orally (by mouth) immediately before birth, the newborn may experience hyperbilirubinemia (jaundice). Your doctor will decide whether the use of this medicine is absolutely necessary or not. Do not use it during the last months of pregnancy. Strictly follow medical instructions.

Animal studies have not shown any direct or indirect adverse effect on the ability to reproduce or to the appearance of defects (malformations) in the offspring.

Due to limited experience and the above-mentioned risks, silver sulfadiazine can only be used with extreme caution in pregnant women or women who are planning pregnancy.

Breastfeeding

Do not use Dermazin cream while breastfeeding if the infant is younger than 2 months, because sulfonamides may pass into breast milk and that can cause side effects (jaundice). If the infant is older, the doctor should consider the ratio of benefits and risks of the treatment.

In premature infants (premature children) and infants who have a deficiency of the enzyme glucose 6-phosphate dehydrogenase, one must take into consideration the increased risk of hyperbilirubinemia (jaundice).

Driving and using machines

This medicine does not affect your ability to drive or use machines.

Other warnings

The cream contains Methylparahydroxybenzoate and Propylparahydroxybenzoate, which may cause allergic reactions (possibly delayed). Dermazin cream contains peanut oil. If you are allergic (hypersensitive) to peanut or soya do not use this medicine.

Dermazin also contains a glycol which may cause skin irritation. Cetyl alcohol may cause local skin reactions (eg. Contact dermatitis).

3. HOW TO USE DERMAZIN

Always use DERMAZIN exactly as indicated in this package leaflet. If you are unsure, please ask your doctor or pharmacist for advice.

Dermazin cream is intended for external and topical use only.

Recommended dosage

Usually, Dermazin cream should be applied once a day. It can be used several times a day for more severe wounds; however, you need to apply the cream at least once a day.

Children

Dermazin cream is not suitable for treatment of neonates and infants younger than 2 months, because the treatment with sulfonamides may cause kernicterus (jaundice).

Method of administration

After the burned area is cleaned and debrided, Dermazin cream is applied to a thickness of 2-4 mm to the burned area or, preferably, the cream is applied to sterile gauze which is placed over the burn wound. The

cream is applied by a sterile spatula or gloved hand. The burned areas are usually covered with the cream once daily; in severe burn wounds the cream is reapplied daily. Duration of superficial burn treatment depends on the injury ranging from several days to one month at the most. Surgery is required only if no healing occurs after one month of treatment with Dermazine.

Prior to each application of the cream, the burn should be washed in shower or with an antiseptic solution to remove remnants of cream and wound exudates which are abundant after Dermazine application, resembling pus in colour but actually aseptic.

Dermazine cream in jars intended for repeated application in one patient only. The application of the cream is painless. It does not stain clothes and bed linen.

If you use more Dermazin cream than you should

If you use more Dermazin cream than prescribed, contact your doctor or pharmacist for advice.

If Dermazin cream is used in high doses and on a large body surface area, it can cause the general side effects of sulfonamides or silver. Side effects should be treated symptomatically.

If you forget to use DERMAZIN

If you forget to use a dose, use it as soon as you remember. Do not apply a double dose next time, but continue taking the medicine as prescribed by your doctor or as indicated in the package leaflet.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

The following listed side effects occur often: skin irritation, burning, itching, pain at the site of administration, rash, decreased white blood cell count (white blood cells) in the blood count, gray skin color. Because of the potential reduction in the number of white blood cells, blood count should be regularly monitored during treatment.

The following listed side effects occur very rarely: life-threatening reactions on the skin (Stevens-Johnson syndrome, toxic epidermal necrolysis) (see Section 2, before you start using Dermazin).

The following listed side effects occur at unknown frequency: hypersensitivity reactions, allergic skin reactions such as rash, itching, dermatitis, which can occur only as a burning sensation or pain at the site of administration or thirst.

If used on larger areas, mainly for the treatment of burns, Dermazin cream can cause side effects which are known to occur with oral (by mouth) use: changes in the blood count, fever, problems with liver and kidneys and crystalluria (the appearance of crystals in the urine). With regard to the individual appearance of these symptoms, their frequency is unknown.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE DERMAZIN

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the tube and carton. The expiry date refers to the last day of that month.

Do not store above 25 °C.

Shelf life: 3 years.

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.

6. FURTHER INFORMATION

What DERMAZIN contains

The active substance is silver sulfadiazine

The other ingredients are hydrogenated peanut oil (peanut oil), cetyl alcohol, Methylparahydroxybenzoate, propylene glycol, Propylparahydroxybenzoate, polysorbate 60, demineralized water.

What DERMAZIN looks like and contents of the pack

1 gram of cream contains 10 mg of silver sulfadiazine.

Dermazin is packed in a tube with 50 g of cream in a box.

Regime of dispensing

The medicine is issued without doctor`s prescription.

Manufacturer

Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Slovenia

Manufacturer of the medicinal product

Lek farmacevtska družba dd, Verovškova 57, Ljubljana, Slovenia

Salutas Pharma GmbH, Lange Gohren 3, Osterweddingen, Germany