Package leaflet:
Information for the patient

Cutadin - S

Cream – 1 %

(Silver sulfadiazine)

Read this leaflet carefully before you start taking this medicine.

- 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 symptoms are the same as yours.
- If any of the side effects gets worse or if you notice any side effect not listed in this leaflet, please inform your doctor or pharmacist.

What is in this leaflet:

1. WHAT CUTADIN - S IS AND WHAT IT IS USED FOR

Cutadin - S contains the active substance silver sulfadiazine, which is a sulfonamide.
Cutadin - S is a local antimicrobial drug with broad spectrum, that acts against some Gram – positive and Gram – negative bacteria, including Pseudomonas aeruginosa, Escherichia coli and the sensible strains of Proteus spp., Staphylococcus spp., Enterobacter spp., Klebsiella spp. and some fungi. It has a bactericidal activity; the silver salt acts in the bacterial cell membrane and wall.

Cutadin - S is used in the:

- prophylaxis and treatment of infection in severe burns;
- treatment of infected ulcers of the skin (leg ulcers and pressure sores).

2. BEFORE YOU USE CUTADIN - S

Do not use Cutadin - S:

- if you are hypersensitive to silver sulfadiazine, to any sulfonamide or to any other excipient of Cutadin - S cream;
- in premature neonates and in neonates in the first months of life, because of the risk of kernicterus;
- during the last trimester of pregnancy;
- during breast – feeding of premature neonates and neonates with jaundice or with glucose - 6 - phosphate dehydrogenase deficiency.

Take special care with Cutadin - S

Special care should be taken in patients with:

- glucose – 6 – phosphate dehydrogenase deficiency, because of the risk of hemolysis;
- significant renal impairment;
- significant hepatic impairment.

When leucopenia occurs at the beginning of the treatment, it is not necessary to stop the use of Cutadin - S cream, but it is recommended to monitor blood count.
The use in large areas of the skin or for a prolonged time of Cutadin - S cream, may increase its systemic concentration causing crystalluria and argyria.

Taking other medicines

Concomitant treatment with other medicines may affect or be affected by Cutadin – S cream.
Please contact your doctor or pharmacist if you are taking / using or have recently taken / used other medicines, including those obtained without a prescription.
It is not recommended the concomitant use of Cutadin - S cream and enzimatic debriding preparations, because the silver content may inactivate the last ones.

Pregnancy and breast - feeding

Cutadin - S cream may be used during the first and second trimester of pregnancy only if the benefit for the mother outweighs the risk for the fetus.
Cutadin - S is contraindicated during the third trimester of pregnancy because of the risk of kernicterus in the neonate.
Cutadin - S cream is contraindicated during breast - feeding of premature neonates and neonates with jaundice or with glucose - 6 - phosphate dehydrogenase deficiency.

Driving and using machinery

Cutadin - S cream has no influence on the ability to drive and use machinery.

Important informations about some of the excipients of Cutadin - S

This medicine contains:

- PEG – 35 castor oil, which may cause skin reactions;
- cetyl alcohol, which may cause local skin reactions (e.g. contact dermatitis);
- propylene glycol, which may cause skin irritation;
- methylhydroxybenzoate, which may cause allergic reactions (possibly delayed).

3. HOW TO USE CUTADIN - S

Always Cutadin - S is used exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
Cutadin - S cream should be applied in the damaged area of the skin wearing sterile gloves.
During the application, if it is necessary, you may also use a sterile spatula.
Before each application, it is necessary to clean the skin with water, saline or antiseptic solution.
Cutadin - S cream is used once or twice daily in a layer approximately 2 – 3 mm thick. In severe cases, the cream can be used 4 times daily.
Treatment should continue until there is an evident wound healing.

If you use more Cutadin - S than you should

If you use more Cutadin - S than you should, or if the children have taken this medicine incorrectly, please contact your doctor or call the hospital or emergency to get an opinion for the risk and an advice for the actions to be taken.
The use in large areas of the skin or for a prolonged time of Cutadin - S cream, may increase its systemic concentration causing crystalluria and argyria.

If you forget to use Cutadin - S

If you forget a dose, use it as soon as you remember it, unless it is time of the application of the next dose.
Do not use a double dose (or higher) to make up for a forgotten dose.
If you have further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all other medicines, Cutadin - S can cause side effects, although not everybody manifests them.
Cutadin – S may be absorbed after local application and cause systemic effects similar to those of the other sulfonamides.
Tell your doctor for the following side effects that may appear to you:

- allergic reactions such as: burning, itching, rash;
- local pain and irritation;
- transient leucopenia;
- argyria, as a result of systemic absorption of silver during use in large areas of the skin and for a prolonged time of Cutadin – S.

If any of the side effects worsens, or if you notice any side effects not mentioned in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE CUTADIN - S

Keep away from children.
Do not use Cutadin - S after the expiry date which is stated on the packaging.
Store below 25°C.
Keep in the original packaging to protect it from light and humidity.

6. OTHER INFORMATION

What Cutadin - S – cream 50 g contains:
The active substance is silver sulfadiazine.
1 g cream contains 10 mg silver sulfadiazine.
Other excipients: cetyl alcohol, PEG - 35 castor oil, white soft paraffin, light liquid paraffin, methyl hydroxybenzoate, propylene glycol, purified water.

Content of the pack:
Carton box with 1 tube of 50 g.

Explanatory of the illustration icons on the packaging:

Without medical prescription.

Content.

Warning.

Cream.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA Sh.a.
Rruga "Myslym Keta"
Tel.Fax: 00355 4 2362800
Tirana - ALBANIA

This leaflet was last revised in January 2015.

SPECIFICATION

CROPING AREA 12 x 19 cm

PAY ATENTION, all the layers are visible.
If you have to print this document please check or uncheck the specific layers.