PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Silver sulfadiazine cream USP 1% w/w - SILVERKANT

Read all of this leaflet carefully before you starts giving 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, health care worker or pharmacist.
- Do not pass it on to others. It may harm them, even if their symptoms are the same.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care worker or pharmacist

In this leaflet:

1. WHAT SILVER SULFADIAZINE CREAM USP 1% W/W SILVERKANT ARE AND WHAT THEY ARE USED FOR

SILVER SULFADIAZINE CREAM USP 1% W/W SILVERKANT are an antibiotic belongs to the class of drugs known as sulfa antibiotics.

It is bactericidal for many gram-negative and gram-positive bacteria as well as being effective against yeast.

2. What you need to know before you use Silver Sulfadiazine Cream USP 1% W/W

You should not use this medication if you are allergic to silver sulfadiazine or another sulfa medication.

If you have any of these other conditions, you may need a dose adjustment or special tests to safely use this medication:

- liver disease;
- kidney disease; or
- an enzyme deficiency called glucose-6-phosphate dehydrogenase deficiency(G6PD).

Pregnancy category B. Silver sulfadiazine is not expected to be harmful to an unborn baby. Tell your doctor if you are pregnant or plan to become pregnant during treatment. It is not known whether silver sulfadiazine passes into breast milk or if it could harm nursing baby. Do not use this medication without telling your doctor if you are breast-feeding baby.

precautions to be taken:

Sensitization to topically applied silver sulfadiazine is rarely predicted or proven by patch testing. Caution should be exercised in the use of Silverkant cream in individuals who have previously shown sensitization reactions to sulfonamides.SILVERKANT may be hazardous in individuals with glucose-6-phosphate-dehydrogenasedeficiency, as hemolysis may occur. In patients with extensive burn areas of the body, the following should be taken into consideration:

(a) complete blood counts may be required prior to and weekly during treatment to detect blood dyscrasias in this patient group; therapy should be discontinued if a significant decrease in the count of any formed blood elements occurs.

(b) considerable amount of silver sulfadiazine is absorbed. Serum concentrations of silver sulfadiazine may approach adult therapeutic levels (8 to 12 mg %). Therefore it is recommended to monitor serum sulfa concentrations. Particular attention must be paid to adequate fluid intake and acid base balances, and renal function should be carefully monitored and urine should be checked for sulfa crystals. Use of SILVERKANT cream may delay separatin of burn eschar and may alter the appearance of burn wounds.

Sulfonamides may precipitate an acute attack of porphyria.

Use in Pregnancy

A reproduction study has been performed in rabbits at doses up to 3-10 times the concentration of silver sulfadiazine present in the cream, and has revealed no evidence of harm to the foetus due to silver sulfadiazine. There are, however, no adequate and well controlled studies in pregnant women

Because animal reproduction studies are not always predictive of human response, this drug should only be used during pregnancy in badly burned pregnant women if the benefit to the mother

outweighs the risk to the foetus. SILVERKANT cream should not be used when the patient is near term since sulfonamide therapy is known to increase the possibility of kernicterus.

Use in Breastfeeding

It is not known whether silver sulfadiazine cream is excreted in human milk. However, sulfonamides are known to be excreted in human milk (15-35% of that in serum), and all sulfonamide derivatives are known to increase the possibility of kernicterus. Because of the possibility for serious adverse reactions in nursing infants from sulfonamides, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into consideration the importance of the drug to the mother.

Use in Paediatrics

Safety and effectiveness in children and infants have not been established. If hepatic or renal functions become impaired and elimination of drug decreases, accumulation may occur. Discontinuation should be weighed against any therapeutic benefit being achieved. Reduction in bacterial colonization has caused delayed separation, in some cases necessitating escharotomy in order to prevent contracture. Leukopenia has been reported following the use of silver sulfadiazine, especially patients with large area burns. This may be a drug-related effect, and often occurs 2-3 days after treatment has commenced. It is usually self-limiting and therapy with SILVERKANT cream does not normally need to be discontinued, as the WBC count usually returns to the normal range in a few days. WBC counts should be closely monitored.

Talk to your doctor before using SILVER SULFADIAZINE CREAM USP 1% W/W

Tell your doctor about all other medications you use, especially cimetidine (Tagamet).
This list is not complete and there may be other drugs that can interact with silver sulfadiazine.
Tell your doctor about all your prescription and over-the-counter medications, vitamins, minerals, herbal products, and drugs prescribed by other doctors

- Nausea, vomiting and diarrhoea
- Skin rash, increasing pain, burning or itching.
- These side effects are usually mild.
- Tell your doctor immediately if you notice any of the following:

- Red, raised bumps on the face and scalp (lupus erythematosus)
- Problems with urine volume or colour (Renal or hepatic toxicity)
- Heart pain (myocarditis),
- Severe abdominal pain (pancreatitis)
- Inflammation of the blood vessels causing nodular swellings along length of vessel
- (vasculitis, including polyarteritis nodosa).
- Allergy-type reactions such as blistering or angry red rash.
- Skin discolouration.

Other medicines and SILVER SULFADIAZINE CREAM USP 1% W/W .

Tell your doctor about all other medications you use, especially cimetidine (Tagamet).
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3. How to use SILVER SULFADIAZINE CREAM USP 1% W/W

"Do not share medicines prescribed for you with any other person."

- Use this medication exactly as prescribed by your doctor. Do not use it in larger amounts or for longer than recommended. Follow the directions on your prescription label.
- Wash your hands before and after applying silver sulfadiazine cream.
- The person applying this medication to burn wounds should wear sterile disposable gloves.
- Take care to keep the treatment area as clean as possible to prevent further infection.
- Clean the area to be treated as directed by your doctor. Apply enough of the medication to cover the affected area evenly.
- Silver sulfadiazine cream should be applied in a layer about one 16th of an inch thick (1.5 millimetre).
- Silver sulfadiazine cream is usually applied 3 to 4 times day. Burn wounds must be kept covered with this medication at all times. Treated skin areas can be left uncovered, or you may use a gauze bandage if directed by your doctor.
- If needed, apply more cream to replace any medication that has come off on bandages, clothing, or bed linens.
- Reapply the cream after bathing or water therapy.
- To be sure this medication is not causing harmful effects, your blood may need to be tested on a regular basis.
- Your kidney function may also need to be tested.

- Do not miss any follow up visits to your doctor.
- Use this medication for the full prescribed length of time.
- Your symptoms may improve before the infection is completely cleared.

4. Possible side effects

- mild itching or burning

Common side effects (may affect up to 1 in 10 people):

- Complication At Treatment Site

Uncommon side effects (may affect up to 1 in 100 people):

- hyperosmolality,
- methemoglobinemia,
- hemolysis

Rare side effects (may affect up to 1 in 1,000 people):

- Decreased Blood Platelets
- Decreased White Blood Cells
- Deficiency Of Granulocytes A Type Of White Blood Cell
- Erythema Multiforme
- Glucose-6-Phosphate Dehydrogenase (G6PD) Deficiency Anemia
- Hemolytic Anemia
- Interstitial Nephritis
- Low Blood Counts Due To Bone Marrow Failure
- Skin Rash With Sloughing
- Stevens-Johnson Syndrome
- Toxic Epidermal Necrolysis

Very rare side effects (may affect up to 1 in 10,000 people):.

- Itching
- Rash
- Skin Discoloration
- Sun-Sensitive Skin

5. How to store SILVER SULFADIAZINE CREAM USP 1% W/W

- Store in a dry place, below 30^0C.
- Protect from light.

Keep SILVERKANT where young children cannot reach it. A locked cupboard at least one and-a-half metres above the ground is a good place to store medicines.
Do not store SILVERKANT or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills.

Disposal

If your doctor tells you to stop using SILVERKANT or it has passed its expiry date, ask your pharmacist what to do with any that is left over

6. Contents of the pack and other information

SILVERKANT is available in Aluminium Collapsible Tube of 15gm which is placed in Printed carton along with the printed insert.

What SILVER SULFADIAZINE CREAM USP 1% W/W SILVERKANT looks like and contents of the pack:

SILVERKANT is available in Aluminium Collapsible Tube of 15gm which is placed in Printed carton along with the printed insert.

Manufactured by:

S Kant
HEALTHCARE Ltd.

1802-1805, G.I.D.C., Phase III,
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