4000003814

QUENCH PLUS Cream

(Silver Sulfadiazine and Sodium Hyaluronate Cream) 1% / 0.2% w/w

Product Specifications: Innovator

Quench Plus Cream 15 g
Each gram contains:
Silver Sulfadiazine U.S.P. ..... 10 mg
Sodium Hyaluronate B.P. ..... 2 mg

Quench Plus Cream 50 g
Each gram contains:
Silver Sulfadiazine U.S.P. ..... 10 mg
Sodium Hyaluronate B.P. ..... 2 mg

Quench Plus Cream 250 g
Each gram contains:
Silver Sulfadiazine U.S.P. ..... 10 mg
Sodium Hyaluronate B.P. ..... 2 mg

DESCRIPTION

Quench plus (silver sulfadiazine and sodium hyaluronate) cream is a synergic combination for promotion of healing and prevention of infection.

CLINICAL PARTICULARS

Therapeutic indications

Quench plus (silver sulfadiazine and sodium hyaluronate) cream is indicate for:

- Local treatment of mild sores
- Local treatment of first- and second-degree burns

Posology

After cleaning the injured parts, apply an even layer of cream 2 or 3 mm thick.
The application should continue as long as there is a possibility of infection and until complete healing.

Method of Administration

- Before applying Quench plus (silver sulfadiazine and sodium hyaluronate) cream, the affected areas should preferably be cleaned with sterile saline (NaCl 0.9%) and disinfected with antiseptics preferably containing povidone iodine or chlorhexidine. Surgical cleaning should be carried out if necessary.
- In the treatment of burns, cleaning of the lesions is preferable to be carried out with water or sterile saline solution only, avoiding disinfection with antiseptic agents before the application of Quench plus (silver sulfadiazine and sodium hyaluronate) cream.
- Quench plus (silver sulfadiazine and sodium hyaluronate) cream is for topical use only. Avoid contact of Quench plus (silver sulfadiazine and sodium hyaluronate) cream with the eye.

Contraindication

Silver sulfadiazine and sodium hyaluronate combination cream is contraindicated in patients who are hypersensitive to sulphonamides, silver sulfadiazine, sodium hyaluronate or other components of the preparation.

WARNINGS

Silver sulfadiazine and sodium hyaluronate combination cream should be used with caution in individuals who have had previous allergies to sulfonamides and in the presence of hepatic or renal impairment.

USE IN SPECIFIC POPULATIONS

Pregnancy and lactation

In the absence of data on the effects of the medicinal product on the foetus, Silver sulfadiazine and sodium hyaluronate combination cream should not be used during pregnancy and lactation unless the physician considers that the therapeutic benefits outweigh the possible risks.

DRUG INTERACTIONS

- Local proteolytic enzymes, applied concomitantly with silver sulfadiazine and sodium hyaluronate combination cream, may be inactivated by the presence of silver ions.
- Do not use concomitantly with disinfectants containing quaternary ammonium salts as hyaluronic acid can precipitate in their presence.

Adverse Reactions

After the application of Silver sulfadiazine and sodium hyaluronate combination cream, local reactions (pain, burning, itching) may occur, including allergic reactions.
Since systemic administration of sulfonamides may result in adverse reactions such as renal failure, toxic hepatitis, agranulocytosis, thrombocytopenia and leukopenia, it cannot be excluded that local treatment of large parts of the body with Silver sulfadiazine and sodium hyaluronate combination cream may give rise to undesirable effects typical of systemically administered sulfonamides.

Effects on ability to drive and use machines

Silver sulfadiazine and sodium hyaluronate combination cream does not affect the ability to drive and use machines.

OVERDOSAGE

No cases of overdose are known.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Pharmacotherapeutic group: Silver sulfadiazine, combinations,
ATC code: D06BA51,
This product is a combination of hyaluronic acid and silver sulfadiazine. Hyaluronic acid is an acidic mucopolysaccharide that makes up more than 50% of the fundamental substance of the dermis; it is also found in high concentrations in the vitreous humor, synovial fluid, umbilical cord and bone cartilage. The local supply of hyaluronic acid accelerates the healing process of the lesions.
Silver sulfadiazine has remarkable antibacterial activity on many gram positive and gram negative germs and on many species of fungi. Its activity on Pseudomonas aeruginosa and Enterobacter pyogenes is remarkable, which are the microorganisms most frequently found in infected wounds and burns.
Thanks to the complementary action of the two active components, this product prevents secondary infection and promotes wound healing.

PHARMACOKINETIC PROPERTIES

The absorption of hyaluronic acid and silver sulfadiazine topically is clinically insignificant. Plasma levels of sulfadiazine are well below the threshold for systemic risks.
After dermal application of a therapeutic dose of Silver sulfadiazine and sodium hyaluronate combination cream, on average, only 1% of the amount of sulfonamide that is absorbed after oral administration of a therapeutic dose of sulfadiazine is absorbed.

PRECLINICAL SAFETY DATA

The LD50-os and i.p. in rats and mice of hyaluronic acid is > 200 mg/kg.
The LD50-os in mice of sulfadiazine is > 10,000 mg/kg.
Chronic toxicity studies of hyaluronic acid, performed on various species of animals, have not highlighted toxicity.
Long-term administration of sulfadiazine resulted in nephrotoxicity only at oral doses very high.
No interference of any kind is established between the active constituents of Silver sulfadiazine and sodium hyaluronate combination cream with regard to any toxic effects.
The combination proved to be devoid of antigenic power and with excellent local tolerability.

Incompatibilities

There are no known incompatibilities.

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. You can also report side effects directly via our website:
https://ferozsons-labs.com/safety-reporting-form/
By reporting side effects, you can help provide more information on the safety of this medicine.

HOW SUPPLIED

Quench Plus Cream 1% / 0.2% w/w: Pack of 15 g, 50 g and 250 g

STORAGE

Do not store above 30°C.
The expiration date refers to the product correctly stored at the required condition.

INSTRUCTIONS:

Keep away from heat, light and moisture.
Keep all medicines out of the reach of children.
To be sold on the prescription of a registered medical practitioner only.
DO NOT USE IN THE EYES.
FOR EXTERNAL USE ONLY.

Please read the contents cautiously before use.
This package insert is regularly and timely updated.

Manufactured by:
FEROZSONS LABORATORIES LIMITED
P.O. Ferozsons, Nowshera-Pakistan
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