

SOFARGEN SPRAY

PATENT PENDING

Cutaneous spray

Product description

Sofargen Spray is a spray powder dressing for topical use containing light kaolin and silver sulfadiazine. Light kaolin creates a mechanical barrier against external agents, protecting wounded skin, and at the same time it draws away and absorbs exudate.

The presence of silver sulfadiazine, a metal-organic compound obtained by the reaction of silver nitrate with sulfadiazine, prevents the microbial contamination of the dressing and maintains the wound environment free from exogenous bacteria.

Sofargen Spray's peculiar formulation thus allows to control exudate by creating an environment which aids the natural healing process and provides an effective barrier to microbial penetration. The product remains easily in place and is not affected by the pulling of the wound edges. It can be easily removed by cleaning the wound with saline solution.

Composition

Light kaolin 9.8 g; micronized silver sulfadiazine 0.1 g; calcium gluconate monohydrate 0.1 g; butane propellant 70.0 g.

Indications

Sofargen Spray is indicated for the local treatment of small skin lesions such as abrasions, excoriations, cuts, superficial wounds and dermatological affections in general.

Dosage and method of use

Shake can well for a few seconds before use. After cleansing the wound, direct the nozzle in its direction, maintaining the can in a vertical position at a distance of approximately 10 cm from the wound. Apply an even layer of **Sofargen Spray** on the wound, pressing the spray nozzle for a few seconds. **Sofargen Spray** must be applied continuously without interruption once or twice a day until the lesion is completely healed. Carefully clean the wound with water or saline solution every time before reapplying **Sofargen Spray**.

The powder contained in **Sofargen Spray** will tend to remain adherent to the wound (due to the exudate present) or to macerated skin, while it will tend to come off freely from dry, healthy skin.

Where desirable or necessary, cover the lesion with a plaster or bandage (according to the size of the wound) after applying **Sofargen Spray**.

Precautions

Patients with known hypersensitivity to its ingredients must not use **Sofargen Spray**.

It is not recommended to use the product for more than four weeks. In case complete healing is not obtained or in the event undesirable symptoms develop, consult a physician.

Protect the face when spraying the product on the upper part of the body. Avoid inhaling the spray powder. In case the powder is accidentally swallowed or inhaled, consult a physician.

Warnings

Due to the silver ions in the formulation, the dispensed powder may tend to darken when exposed to light. This occurrence does not compromise its efficacy or safety.

Do not apply the product together with liquid or solid disinfectants. Replace the cap on the can after each use.

The product should not be used in pregnant women and infants unless recommended by a physician.

Sofargen Spray is to be used for the treatment of small lesions only.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

Undesirable effects

A temporary irritation or burning sensation may occur, although without consequences and rare local allergic reactions.

In the event any undesirable effects occur, consult a physician or pharmacist.

Expiry and storage

Store at a temperature below 40°C.

Do not use the product after the expiry date indicated on the can. The expiry date refers to the product in unopened, correctly stored packs. The can is a pressurized container and is flammable: do not puncture or in any way tamper with the can, even when it is empty. The product contains an inflammable propellant under pressure: do not use near flames or heat. Do not store under direct sunlight. The can may explode if exposed to temperatures above 50°C. Dispose the can after use according to current regulations. Does not contain propellant gasses dangerous for the ozone.

Packaging:

125 ml pressurized can containing 10 g of spray powder.

Manufacturer:

Soveta Baltica UAB

Via Kalvariju 125

08221 Vilnius, Lithuania

Distributed by:

SOFAR S.p.A.

Via Firenze 40

20060 Trezzano Rosa (MI), Italy

Contents 125 ml