# SUMMARY OF PRODUCT CHARACTERISTICS

# IONSIL

# (Silver Nitrate Gel)

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**IONSIL**
(Silver Nitrate Gel)

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**1. Name of the medicinal product**

**1.1 Name of the medicinal product**

**Generic Name** **:** Silver Nitrate Gel 0.2%

**Brand Name** **:** IONSIL

**1.2 Strength** **:** 0.2%

**1.3 Pharmaceutical form** **:** Topical-Ointment

**2. Qualitative and quantitative composition**

**Formulation:** Silver Nitrate Gel

**Composition:**
Each gram contains –
Silver Nitrate USP 2.0 mg

**Shelf Life:** 2 Years (24 Months)

For the full list of excipients, see section 6.1.

**3. Pharmaceutical form**

**Form:** Topical Gel

**Physical Description:** White colored gel

## 4. Clinical particulars

### 4.1 Therapeutic indications

IONSIL antimicrobial wound gel is indicated for use in wounds with light to moderate exudates such as:

- Pressure ulcers
- Diabetic foot ulcers
- Leg ulcers
- Skin tears
- 1st and 2nd degree burns
- Grafted wounds and donor sites
- Surgical wounds
- Lacerations and abrasions

### 4.2 Posology and method of administration

IONSIL gel is applied as a 1 mm thick layer over the wound surface. Application procedure is detailed below:

1. Cleanse the wound using sterile saline or appropriate wound cleanser
2. Dispense IONSIL gel to an appropriate clean applicator such as a tongue depressor or gauze in sufficient quantity to liberally cover the wound. Spread the gel on the wound.
3. Cover the gel with an appropriate secondary dressing such as a gauze pad, film or nonwoven adhesive secondary dressing.
4. As IONSIL is a multiple application tube, it needs to be closed tightly after each use.

### 4.3 Contraindications

**IONSIL is contraindicated in patients with:**

- Hypersensitivity to the active substance or to any of the excipients.
- Moderately to heavily exudating wounds.
- Bleeding wound.
- Skin rash caused by an allergic reaction to food and medicine.

### 4.4 Special warnings and precautions for use

IONSIL should be restricted for topical use. It should not get into contact with eyes, nose, or mouth. If it gets into eyes, rinse right away with cool tap water.

- It should be kept out of reach of children.
- Do not use more than the recommended dose or for prolonged duration without
- checking with your doctor.
- Frequent or prolonged use of this preparation may result in discoloration of skin and
- mucous membranes.
- Consult your doctor before using any other medicines or cleansers on your skin.
- Consult your doctor, if your symptoms do not get better or if they get worse.

**4.5 Interaction with other medicinal products and other forms of interaction**

Topical preparations containing heavy metals such as silver and mercury should not be used on wounds treated with either papain or collagenase. Papain may get inactivated by the salts of heavy metals such silver. The enzymatic activity of collagenase may be adversely affected by heavy metal ions such as mercury and silver. When it is suspected such products have been used, the site should be carefully cleansed by repeated washings with normal saline before application of collagenase. Clinical and experimental studies indicate that percutaneous absorption of silver is exceedingly low. There are no reported systemic drug interactions.

**4.6 Pregnancy and lactation**

There is no published data on the use of silver nitrate in pregnant women. The effects, if any on the developing fetus are unknown. Until more information in available, silver nitrate should only be used during pregnancy if the maternal condition justifies the potential risk to the fetus.

Reports describing the use of silver nitrate during human lactation are not available and the effects on the nursing infant from exposure to the drug in milk are unknown. Risk to the infant should be considered relative to the inherent toxicity of the drug.

**4.7 Effects on ability to drive and use machines**

Not applicable

**4.8 Undesirable effects**

Like any other medicine IONSIL may cause side effects, but many people have no, or minor, side effects. Pain, burning, or itching of the treated skin may occur. Following are some of the uncommon adverse effects:

Severe allergic reactions (rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue); excessive or sudden bleeding, burning, itching, irritation, pain, redness, or swelling of the skin; fever.

Reporting of suspected adverse reactions:
Reporting suspected adverse reactions after authorisation of the medicinal product is important as it allows continued monitoring of the benefit–risk balance of the medicinal product. Healthcare professionals are requested to report any suspected adverse reactions to the relevant National Regulatory Authority.

**4.9 Overdose**

There is limited experience with over dosage. If overdose is suspected, depending upon the adverse event appropriate symptomatic treatment has to be provided.

## 5. Pharmacological properties

### 5.1 Pharmacodynamics properties

To be effective, the silver complex contained in a silver-based product must release biologically active silver ions. Silver ions interact with a number of cellular components of bacteria, protozoa and fungi, thereby producing inhibition of growth, loss of infectivity to cell death. Silver ions interact with sulfhydryl (-SH) groups of proteins as well as bases of DNA leading either to the inhibition of respiratory processes or DNA unwinding. Silver also produces inhibition of cell division and damage to bacterial cell envelops, in addition to interaction with hydrogen bonding process. It is also known to inhibit a number of oxidative enzymes such as yeast alcohol dehydrogenase, the uptake of succinate by membrane vesicles and respiratory chain of *E coli*, as well as causing metabolite efflux.

The most important targets of silver at low concentrations appear to be the sodium translocating NADH: ubiquinone oxidoreductase system. In yeast and fungi, interruption of cell wall results in loss of essential nutrients. Overall, the surface binding and damage to membrane function are the most important mechanisms for the killing of bacteria by silver.

### 5.2 Pharmacokinetic properties

Topical silver nitrate has very limited penetration through the skin and is not absorbed

### 5.3 Preclinical safety data

Acute toxicity study was performed to assess the systemic toxic effects of IONSIL gel. New Zealand albino rabbits of either sex were used. A single dose of IONSIL gel was administered sub-cutaneously and the animals were observed for a period of 14 days for potential morbidity and mortality if any. Blood samples were collected on day 7 and 14 for hematology and clinical chemistry analysis. Animals were necropsied and vital organs were weighed and subjected to histopathological examination at the end of the study period. In the 14 days of study period no mortality or morbidity was observed in any group.

Statistically significant differences were not observed in control and test group animals in terms of body weight, food intake, water consumption live phase physical activity and neurological behavioral parameters. Abnormal clinical signs were not observed at the site of drug administration. Biochemical and hematological parameters of control and test group were comparable and within the normal physiological range. Histopathology observation of vital organs did not reveal any significant differences between the control and test group animals.

A guinea pig maximization test was performed using IONSIL gel preparation to evaluate the potential for delayed dermal contact sensitization. IONSIL gel was intradermally injected and topically applied to 10 test guinea pigs in an attempt to induce delayed sensitization (Induction I and II). A control solution of PBS (Phosphate Buffered Saline)

was similarly injected and topically applied to 5 control guinea pigs. Following a recovery period, all the test and control animals received a challenge patch and a challenge by intradermal injection. All sites were scored at 24 and 48 hours after a patch removal and after injection. The topical application and intradermal injection of the IONSIL gel did not induce delayed sensitization in the guinea pig. IONSIL gel was evaluated for intracutaneous irritation in accordance with the ISO guidelines. The purpose of this test was to determine the intracutaneous irritation potential of the test article when injected into the skin of the rabbit. 60 minutes after the treatment, in all animals treated with extraction of the test material in vegetable oil, slight erythema without edema was observed. The erythema has totally disappeared after 24 hours of treatment. Based on the results, interpreted according to ISO 10993-10:2002, the test substance IONSIL gel can be considered as a non-irritant for skin.

The *in vitro* cytotoxicity test was conducted on cultured mouse fibroblast 3T3-L1 cell lines. Under the conditions of the study, IONSIL gel does not exert any cytotoxic effects on 3T3-L1 mouse fibroblast cells after 48 hours of exposure.

## 6. Pharmaceutical particulars

### 6.1 List of excipients

| Sr. No. | Name of Materials | Specification |
|---|---|---|
| 1 | Polyacrylamide | IHS |
| 2 | Methyl paraben | USP |
| 3 | Propyl paraben | USP |
| 4 | Glycerol | USP |
| 5 | Guar gum | USP |
| 6 | Ethanol | USP |
| 7 | Sodium chloride | USP |
| 8 | Purified water | USP |

### 6.2 Incompatibilities

All the excipients used are accepted pharmacopeial excipients and their usage in the particular hydrophilic gel preparation is registered in the USP/IP. **IONSIL GEL** is supplied in an inner laminated tube **(PE)**. This finished drug product is non-reactive to the primary packing material. Thus, there are no incompatibilities between the excipients, APIs and container closure system.

### 6.3 Shelf life

24 months

### 6.4 Special precautions for storage

Store below 30°C. Do not freeze.

### 6.5 Nature and contents of container

**IONSIL** is filled in to an inner laminated Polyethylene Tubes of 15 gm & 100g capacity. These tubes are made of 5 layers with extrusion lamination process. The innermost layer is *SEALANT LAYER*, made up of *Special Sealant Medium Density Poly Ethylene layer*, its thickness is *88.0 micron*. This layer is followed by *TIE LAYER*, made up of *Acid Co Polymer*; its thickness is *30.0 micron*. This layer is followed by *BARRIER LAYER*, made up of *Aluminum Foil*; its thickness is *12.0 micron*. This layer is followed by *TIE LAYER*, made up of *Acid Co Polymer*; its thickness is *30.0 micron*. This layer is followed by *WHITE POLY ETHYLENE LAYER*, made up of *Medium Density Poly Ethylene*; its thickness is *120.0 micron*. Polyethylene protects the drug product from light and moisture. Closure (cap) is made up of *POLYPROPYLENE.* These tubes are filled with the IONSIL gel and

heat sealed to prevent any leakages. These tubes are packed in to mono tube cartons along with literature inserts. These individual tubes are packed in to mono cartons of 250 to 350 GSM with laminated outer surface.

## 7 Marketing Authorization Holder

| | | |
|---|---|---|
| **Name** | **:** | VIRCHOW HEALTHCARE PRIVATE LIMITED |
| Address | **:** | 901, DLH Park, S.V. Road,<br>Goregaon (West), Mumbai – 400062. INDIA |
| Tel. | **:** | 91 22 28795600/53 |
| Fax | **:** | 91 22 28724855 |
| Email | **:** | regulatorymgr@virchowhealthcare.com |

## 8 Marketing Authorization Number

H2008/1924/458

## 9 Manufacturer Name

| | | |
|---|---|---|
| **Name** | **:** | VIRCHOW BIOTECH PRIVATE LIMITED |
| **Address** | **:** | Survey No.172 Part, Gagillapur(V),<br>Dundigal-Gandimaisamma (M), Medchal- Malkajgiri (D),<br>Telangana-500043, India |
| **Fax** | **:** | +91-8418255131 |
| **E-mail** | **:** | regulatorymgr@virchowhealthcare.com |

## 10 Date of first authorization/renewal of the authorization

06/05/2026