SUMMARY OF PRODUCT CHARACTERISTICS

Septal Scrub®

1 NAME OF THE MEDICINAL PRODUCT

Septal Scrub®

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Chlorhexidine Gluconate 4% w/v.

3 PHARMACEUTICAL FORM

Solution -External.

Clear or slightly opalescent, viscous red liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

- Antiseptic hand wash
- Pre-operative Surgical Scrub
- Pre-operative Skin Preparation

4.2 Posology and method of administration

Antiseptic hand wash - wet the hands and forearms, apply 5 ml of skin cleanser and wash for one minute. Rinse thoroughly and dry.

Pre-operative Surgical Scrub - wet hands and forearms, apply 5 ml of skin cleanser and wash for one minute, cleaning the finger nails with a brush. Rinse and repeat the procedure using a further 5 ml of skin cleanser and wash for 2 minutes. Rinse thoroughly and dry.

Pre-operative Skin Preparation - the patient should wash his whole body with 25 ml of the cleanser on at least two occasions, usually the day before and on the day of the operation.

4.3 Contraindications

Avoid contact with eyes, middle ear, brain and meninges.

Known hypersensitivity-to the product or any of its components, especially in those with a history of possible chlorhexidine-related allergic reactions (see sections 4.4 and 4.8).

4.4 Special warnings and precautions for use

For external use only.
Keep out of the reach and sight of children.
Do not use in body cavities.

The use of chlorhexidine solutions, both alcohol based and aqueous, for skin antisepsis prior to invasive procedures has been associated with chemical burns in neonates. Based on available case reports and the published literature, this risk appears to be higher in preterm infants, especially those born before 32 weeks of gestation and within the first 2 weeks of life.

Remove any soaked materials, drapes or gowns before proceeding with the intervention. Do not use excessive quantities and do not allow the solution to pool in skin folds or under the patient or drip on sheets or other material in direct contact with the patient. Where occlusive dressings are to be applied to areas previously exposed to Septal Scrub, care must be taken to ensure no excess product is present prior to application of the dressing.

Septal Scrub must not come into contact with the eye. Serious cases of persistent corneal injury, potentially requiring corneal transplant, were reported following accidental ocular exposure to chlorhexidine containing medicinal products despite taking eye protective measure due to migration of solution beyond the intended surgical preparation area. Extreme care must be taken during application to ensure that Septal Scrub does not migrate beyond its intended application site into the eyes. Particular careshould be taken in anaesthetised patients, who are unable to immediately report ocular exposure. If Septal Scrub comes into contact with the eyes, wash out promptly and thoroughly with water. An ophthalmologist's advice should be sought.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

No special precautions need to be taken when used in pregnancy and lactation.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Immune disorders

- Frequency not known

- Hypersensitivity including anaphylactic shock (see sections 4.3 and 4.4) to chlorhexidine gluconate or amine oxide, particularly on repeated use.

Skin disorders

Frequency not known:

– Allergic skin reactions such as dermatitis, pruritus, erythema, eczema, rash, urticarial, skin irritation, and blisters.
– Chemical burns in neonates.

Eye Disorder

Frequency not known:

- Corneal erosion, epithelium defect/corneal injury, significant permanent visual impairment*

System Organ Class	Very common (≥1/10)	Common (≥ 1/100 < 1/10)	Uncommon (≥ 1/1,000 < 1/100)	Rare (≥ 1/10,000 < 1/1,000)	Very rare (< 1/10,000)	Not known (cannot be estimated from available data)
Immune System Disorders						Hypersensitivity Anaphylactic shock
Skin and Subcutaneous Tissue Disorders						Allergic skin reactions Chemical burns neonates

Eye Disorder						Corneal erosion, epithelium defect/corneal injury, significant permanent visual impairment*

*Cases of severe corneal erosion and permanent significant visual impairment due to inadvertent ocular exposure have been reported post-marketing, leading to some patients requiring corneal transplant (see section 4.4).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form https://sideeffects.health.gov.il

4.9 Overdose

Chlorhexidine is poorly absorbed. If swallowed treat with gastric lavage. Employ supportive measures as appropriate.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Chlorhexidine is a bisbiguanide disinfectant which is active against a wide range of Gram-positive and Gram-negative vegetative bacteria. It is also active against some viruses and fungi. It is most active at neutral or slightly acid pH.

5.2 Pharmacokinetic properties

Percutaneous absorption of chlorhexidine gluconate is negligible and leads to clinically insignificant plasma concentrations.

5.3 Preclinical safety data

Preclinical data reveal no special hazard for humans based on conventional studies of repeated dose toxicity, carcinogenic potential and toxicity to reproduction.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Pluronic PE 6800
Ammonyx M
Isopropanol
D-gluconolactone
Herbacol 15.393/T(B)
Spectracol ponceau 4R
Sodium hydroxide (for pH adjustment)

Purified water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

6.4 Special precautions for storage

Store below 25°C.

The product can be used for up to 2 months after first opening the bottle.

6.5 Nature and contents of container

Septal Scrub is packaged in a 500ml HDPE bottle.

6.6 Special precautions for disposal

Not applicable.

7 LICENCE HOLDER AND MANUFACTURER

7. 1 MANUFACTURER:

Vitamed Pharmaceutical Industries Ltd., P.O.B. 114, Binyamina

7.2 LICENSE HOLDER:.

Teva Israel Ltd, Tel Aviv

8 REGISTRATION NUMBER

043.08.23618

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