SUMMARY OF PRODUCT CHARACTERISTICS

SEPTOL

1. NAME OF THE MEDICINAL PRODUCT

Septol

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Chlorhexidine Gluconate 0.5% w/v

Ethanol 70% w/v

3. PHARMACEUTICAL FORM

Solution – External

Clear light blue solution with a residual pleasant odor.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Antiseptic hand rub.

4.2 Posology and method of administration

This product is applied topically.

4.3 Contraindications

Do not use in patients with a known hypersensitivity to the product or any of its components listed in section 6.1, especially in those with a history of possible chlorhexidine-related allergic reactions (see sections 4.4 and 4.8).

Do not use in contact with eyes, brain, meninges, middle ear or external ear with a perforated tympanic membrane.

Do not inject.

Do not use in body cavities.

4.4 Special warnings and precautions for use

Septol contains chlorhexidine. Chlorhexidine is known to induce hypersensitivity, including generalized allergic reactions and anaphylactic shock. The prevalence of chlorhexidine hypersensitivity is not known, but available literature suggests this is likely to be very rare. Septol should not be administered to anyone with a potential history of an allergic reaction to a chlorhexidine-containing compound (see section 4.3 and 4.8).

Accidental ingestion: chlorhexidine is poorly absorbed orally. Treat with gastric lavage using milk, egg white, gelatine or mild soap. Employ supportive measures as appropriate.

Accidental intravenous infusion – blood transfusion may be necessary to counteract hemolysis.

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, the risk appears to be higher in preterm infants, especially those born before 32 weeks of gestation and within the first 2 weeks of life.

4.5 .Interactions with other medicinal products and other forms of interaction

None stated.

4.6 Pregnancy and lactation

None stated.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Immune disorders
Frequency not known:
- Hypersensitivity including anaphylactic shock (see sections 4.3 and 4.4).

Skin disorders
Frequency not known:
- Allergic skin reactions such as dermatitis, pruritus, erythema, eczema, rash, urticarial, skin irritation, and blisters.
- Chemical burns in neonates and infants.

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 and infants)**

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

None stated.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

None stated.

5.2 Pharmacokinetic properties

None stated.

5.3 Preclinical safety data

None stated.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerin

Citron D 3009 IF

D-Gluconolactone

FD & C Blue No.1

Water for injections

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

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

The preparation can be used for up to 6 months after first opening the bottle.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Septol is packaged in a 500 ml HDPE bottle with a cap closure.

6.6 Special precautions for disposal

Not applicable.

7. LICENCE HOLDER AND MANUFACTURER:

- **Manufacturer**: Vitamed Pharmaceutical Industries Ltd, Israel, P.O.B 114, Binyamina, Israel

License Holder: Teva Israel Ltd., Tel-Aviv

8. REGISTRATION NUMBER(S)

029.79.25425

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