

## 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.

When use is to be followed by diathermy do not allow pooling of the fluid to occur and ensure that the skin and surrounding drapes are dry.

##### 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.

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 of sheets or other material in direct contact with the patient. Where occlusive dressing are to be applied to areas previously exposed to Septol, care must be taken to ensure no excess product is present prior to application of the dressing.

Septol 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 Septol does not migrate beyond its intended application site into the eyes. Particular care should be taken in anaesthetised patients, who are unable to immediately report ocular exposure. If Septol comes into contact with the eyes, wash out promptly and thoroughly with water. An ophthalmologist's advice should be sought.

#### **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.

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 and infants)
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

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 product can be used for up to 6 months after first opening of 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

**Revised in August 2024.**