



**PATIENT PACKAGE INSERT
IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS
(PREPARATIONS) - 1986**

The medicine is dispensed without a doctor's prescription

Septal Scrub®

Antiseptic solution
For external use

Composition

Chlorhexidine Gluconate 4% w/v

For information about the inactive ingredients, see section 6 - "Further Information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

Use the preparation in accordance with the instructions in the directions for use section in this leaflet. Consult the pharmacist if you need further information.

1. WHAT IS THE MEDICINE INTENDED FOR?

- Antiseptic hand wash
- Pre-operative surgical hand disinfection
- Pre-operative skin disinfection

Therapeutic group: Antiseptics.

2. BEFORE USING THE MEDICINE

Do not use the preparation:

- If you are sensitive (allergic) to the active ingredient or any of the additional ingredients contained in the medicine, especially in patients with a history of possible allergic reactions connected to chlorhexidine.
- If there is a suspicion of contact with the eyes, the middle ear, the brain and meninges (the tissue covering the brain and spinal cord).

Special warnings regarding use of the medicine

- Do not use in body cavities (e.g., nose or ears).
- Use with care in newborns, especially those born prematurely. Septal Scrub could cause chemical skin burns.
- Remove any absorbent cloth, fabric or clothing before proceeding to surgery. Do not use excessive quantities and do not

allow the solution to collect in the skin folds or under the patient or to drip onto sheets or anything else that is in direct contact with the patient. When dressings need to be applied to areas of skin previously exposed to Septal Scrub, care must be taken to ensure that no excess solution remains before dressing the area.

- Do not allow contact with the eyes due to the risk of visual damage. If it comes into contact with the eyes – wash immediately and thoroughly with water. In case of irritation, redness or pain in the eye, or visual disturbance, refer promptly for medical advice. Serious cases of persistent corneal injury (injury to the surface of the eye) potentially requiring corneal transplant have been reported when similar products have accidentally come in contact with the eye during surgical procedures, in patients under general anesthetic (deep painless sleep).

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

Note

Do not swallow! This medicine is intended for external use only.

Directions for use:

Do not dilute the solution.

Antiseptic hand wash:

1. Wet the hands and forearms
2. Add 5 ml of undiluted Septal Scrub and wash hands for one minute
3. Rinse well with water
4. Dry hands well

Hand disinfection before surgery:

1. Wet the hands and forearms
2. Add 5 ml of undiluted Septal Scrub and wash hands for one minute
3. Clean fingernails with a brush
4. Rinse hands with water
5. Repeat the procedure once more for 2 minutes
6. Rinse well with water
7. Dry hands well

Skin disinfection for patients who are about to undergo an operation:

1. Wash the whole body with 25 ml of Septal Scrub at least twice, usually once the day before the operation and a second time on the day of the operation
2. Rinse well with water
3. Dry the body well

Do not exceed the recommended dosage.

If you accidentally swallow Septal Scrub

If you accidentally swallowed Septal Scrub, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them. If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Septal Scrub may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them. In rare cases chlorhexidine could cause hypersensitivity, including anaphylactic shock (throat or lip swelling and low blood pressure).

Side effects of unknown frequency:

- Allergic reactions (e.g., skin inflammation, itching, redness, eczema, rash, hives, skin irritation, blisters).
- Corneal injury (injury to the surface of the eye) and permanent damage to the eyes including permanent visual impairment (due to accidental exposure of the cornea of the eyes during head, face and neck surgeries) in patients under general anesthetic (deep painless sleep).

Side effects in newborns:

Chemical burns can occur in newborns and babies (frequency unknown). If any of these reactions occur, stop the use and refer immediately to receive medical treatment.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting side effects

Side effects may be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month. **Store below 25°C.**

Can be used for 2 months after first opening, but not beyond the expiry date of the preparation.

6. FURTHER INFORMATION

• In addition to the active ingredient, the medicine also contains:

Pluronic PE 6800, ammonyx M, isopropanol, D-gluconolactone, herbacol 15.393/T(B), spectracol ponceau 4R, sodium hydroxide (for pH adjustment), purified water.

• What the medicine looks like and contents of the package:

A viscous, clear to slightly opalescent, red colored liquid.

Each bottle contains 500 ml of solution.

Name of Manufacturer:

Vitamed Pharmaceutical Industries Ltd., Binyamina.

License Holder and its Address:

Teva Israel Ltd., Tel Aviv.

Revised in August 2024.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 043.08.23618.00

teva

SEPTAL SCRUB PL SH0824

