

PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS

(PREPARATIONS) – 1986

This medicine is dispensed without a doctor's prescription

Septadine Solution

Composition:

Chlorhexidine Digluconate 0.5% w/v
Alcohol 70% v/v

Inactive ingredients and allergens in the medicine – see section 6 “Additional information”.

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any other questions, refer to the doctor or the pharmacist.

Use the medicine according to the instructions in section 3 – “How should you use the medicine?” in this leaflet. Consult the pharmacist if you need more information. Refer to the doctor if signs of the ailment (symptoms) worsen or do not improve.

1. What is the medicine intended for?

The medicine is intended for quick disinfection of hands, including before invasive medical procedures.

Therapeutic class: antiseptic agents.

2. Before using the medicine

Do not use this medicine:

- If you are sensitive (allergic) to the active ingredients chlorhexidine digluconate and/or alcohol or to any of the other ingredients this medicine contains (see section 6 “Additional information”). Especially in patients with a history of possible allergic reactions related to chlorhexidine.
- In contact with the eyes, brain, brain

membranes, middle ear or outer ear when the eardrum is perforated.

- By injection.
- In the openings of the body (such as: nose, ears).
- When diathermy (a type of surgical instrument) is used after using Septadine – make sure there is no accumulation of Septadine and that the skin and any fabric close to the patient are dry.

Special warnings regarding the use of the medicine

- Septadine contains chlorhexidine. Chlorhexidine is known to cause hypersensitivity, including general allergic reactions and anaphylactic shock. The prevalence of hypersensitivity to chlorhexidine is not known. Do not use Septadine in patients with a possible history of allergic reaction to a compound containing chlorhexidine.
- If the medicine is accidentally given by infusion – blood transfusion may be necessary in order to neutralize hemolysis.
- Disinfecting the skin before invasive procedures using chlorhexidine solutions, whether alcohol-based or water-based, has been associated with chemical burns in newborns. The risk appears greater in premature babies, especially those born before week 32 of pregnancy and during the first two weeks of life.
- Do not bring the product near sources of heat or fire.
- Do not light a cigarette or expose yourself to fire before the preparation has completely dried.
- Do not allow contact with the eyes due to the concern of damaging eyesight. If contact with the eyes occurs – wash immediately and thoroughly with water. In case of irritation, redness, pain in

the eye or visual disturbances, seek medical advice immediately.

Serious cases of persistent corneal injury (damage to the eye surface), which may require corneal transplantation, have been reported when similar products have accidentally come into contact with the eye during surgical procedures, in patients under general anesthesia (deep sleep without pain).

Drug interactions:

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

Important information about some of the ingredients of the medicine

The medicine contains 15 mg propylene glycol in each dose (3 ml).

3. How should you use the medicine?

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the medicine.

Do not exceed the recommended dose. Method of administration:

Do not swallow! This medicine is intended for external use only. Avoid contact with the eyes and with mucous membranes. In case of contact wash with plenty of water and refer to a doctor if necessary.

Method of use:

Pour 3 ml of the preparation onto clean hands, spread the solution over the entire surface of the hand and rub your hands together until the substance is completely evaporated.

If you accidentally swallowed this medicine or if a child accidentally swallowed this medicine, immediately go to the doctor or 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 every

time you take a medicine. Wear glasses if you need them.

If you have any other questions regarding the use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, using Septadine may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Immediately stop using the medicine and seek medical attention if the following effects occur:

- Chlorhexidine can very rarely cause hypersensitivity including anaphylactic shock (swelling of the throat or lips, low blood pressure).

Additional side effects with unknown frequency:

- Allergic reactions (e.g., inflammation of the skin, itch, redness, eczema, rash, hives, skin irritation, blisters).
- Corneal damage (damage to the eye surface) and permanent eye damage including permanent visual impairment (due to accidental exposure of the eyes during head, face and neck surgery) in patients under general anesthesia (deep sleep without pain).

Side effects in newborns:

- Chemical burns may occur in newborns and infants (unknown frequency).

If any of these reactions occur, stop using the preparation and seek immediate medical attention.

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

Reporting side effects

Side effects may be reported to the Ministry of Health by clicking on the link “Report side effects due to medicinal treatment” found on the Ministry of Health website homepage (www.health.gov.il),

which will direct you to the online form for reporting side effects, or by clicking on the following link:

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

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. Date) appearing on the package. The expiry date refers to the last day of that month.

Storage conditions:

- Store in a cool place, at a temperature below 25°C.
- Close tightly.
- Caution! Flammable substance, keep away from fire.
- After opening for the first time, the medicine can be used up to the expiry date appearing on the package.

6. Additional information

In addition to the active ingredients the medicine also contains:

Purified water, Glycerin, Propylene Glycol (E1520), Brilliant Blue.

What does the medicine look like and what are the contents of the package?
Blue solution.

Content: 500 ml, 1000 ml.

Not all package sizes may be marketed.

Manufacturer and marketing authorization holder:

Ben Shimon Floris Ltd., Industrial Park Misgav, D.N. Misgav 2017400, Israel.

This leaflet was revised in 02/2025 in accordance with the Ministry of Health guidelines.

Registration number of the medicine in the national drug registry of the Ministry of Health: 108-58-29253-00