

**PATIENT LEAFLET IN ACCORDANCE
WITH THE PHARMACISTS'
REGULATIONS (PREPARATIONS) –
1986**

This medicine is dispensed without a doctor's prescription

Septadine Tarhitz Lotion

Composition:

Chlorhexidine digluconate 4% w/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 symptoms of the ailment worsen or do not improve.

1. What is the medicine intended for?

- Antiseptic hand washing
- Disinfection of hands prior to surgery
- Disinfection of skin for patients who are about to undergo surgery

Therapeutic class: antiseptic preparations.

2. Before using the medicine Do not use this medicine:

- If you are sensitive (allergic) to the active ingredient chlorhexidine digluconate or to any of the additional components the medicine contains (see section 6 "Additional information"). Especially in patients with a history of possible allergic reactions related to chlorhexidine.
- If there is a concern that the medicine will come into contact with the eyes, the middle ear, the brain and the

meninges (the tissue that covers the brain and the spinal cord).

Special warnings regarding the use of the medicine

- Do not use in body cavities (such as nose or ears).
- Use cautiously in newborns, especially those born prematurely. Septadine Tarhitz may cause chemical skin burns.
- Remove any absorbent fabric, woven textile or clothes before proceeding to the surgery. Do not use excessive amounts and do not allow the lotion to pool in skin folds or under the patient or drip on sheets or on anything else that is in direct contact with the patient. When it is necessary to apply dressings to areas of the skin exposed to Septadine Tarhitz, exercise caution and make sure that no excess lotion remains before dressing the area.
- 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 or 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.

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.

How to take the medicine:

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

Method of use:

Do not dilute the lotion.

For antiseptic hand washing:

1. Wet your hands and arms
 2. Add 5 ml of undiluted Septadine Tarhitz and wash your hands for one minute
 3. Rinse thoroughly with water
 4. Dry your hands thoroughly
- ### **For disinfection of hands prior to surgery:**
1. Wet your hands and arms
 2. Add 5 ml of undiluted Septadine Tarhitz and wash your hands for one minute
 3. Clean your nails with a brush
 4. Rinse your hands with water
 5. Repeat this procedure one more time for 2 minutes
 6. Rinse thoroughly with water
 7. Dry your hands thoroughly

For disinfection of skin for patients who are about to undergo surgery:

1. Wash the whole body with 25 ml of Septadine Tarhitz, at least twice, usually once on the day before surgery and a second time on the day of surgery
 2. Rinse thoroughly with water
 3. Dry the body thoroughly
- If you swallowed the medicine by mistake or if a child swallowed this medicine by mistake, 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 Tarhitz 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.

Rarely, chlorhexidine may cause hypersensitivity, including anaphylactic shock (swelling of the throat or lips and low blood pressure).

Additional side effects with unknown frequency:

- Allergic reactions (for example inflammation of the skin, itching, 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 surgeries) 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 treatment.

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 your 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.

6. Additional information

In addition to the active ingredients the medicine also contains

Purified Water, Poloxamer, Lauramine Oxide, Isopropyl Alcohol, Ponceau 4R (E-124), Fragrance.

What does the medicine look like and what are the contents of the package?
Clear red liquid.

Content: 100 ml, 500 ml.

Manufacturer and license holder:

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

This leaflet was revised in 11/2025 in accordance with the Ministry of Health guidelines.

Registration number of the medicine in the national drug registry of the Ministry of Health:
112-44-29484-00

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