Patient package insert in accordance with the Pharmacists' Regulations (Preparations) - 1986

Non-prescription medicine

Septadine

Composition:

Active substances and their concentration: Chlorhexidine Gluconate 0.5% w/v Alcohol 70% v/v

For the list of the inactive substances: See Section 6 "Additional information". Read the insert carefully to the end before using the medication.

This insert contains abridged information on the medicine.

If you have further questions, consult your doctor or pharmacist.

Use the preparation correctly. Consult your pharmacist if you require additional information.

What the medicine is used for ?

This medicine is indicated for rapid disinfection of hands.

Therapeutic Group - Antiseptic prepara-

2. Before using the medicine

X Do not use the medicine:

- If you are sensitive (allergic) to the active substance or to any of the additional ingredients contained in the medicine. For the list of the inactive substances - see Section 6 "Additional information".
- On the brain tissues, meninges and middle ear.
- In infants less than two month of age.

Special warnings concerning use of the medicine:

- Avoid contact with the eyes. In case of contact, rinse thoroughly with water.
- · If you are sensitive to any food or medicine, inform your physician before using this medicine
- Do not light a cigarette or expose yourself to an open flame until the preparation is fully dried.

If you are taking, or recently took, other medicines, including over the counter medicines and dietary supplements, inform your doctor or pharmacist.

Ill Important information about some of the ingredients of the medicine:

Contains alcohol, flammable substance.

3. How to use the medicine?

Ask your doctor or pharmacist if you are not

The generally recommended manner of use is: Dispense 3 ml of the preparation onto clean hands, spread the solution over all hand surfaces and rub hands together until the substance is completely evaporated.

Do not exceed the recommended dosage. Do not swallow. For external use only.

If you have taken an overdose or if a child has accidentally swallowed the medicine, go immediately to a doctor or a hospital emergency room and bring the medicine package with you.

Do not take medicines in the dark!

Check the label and the dose each time you take your medicine.

Wear glasses if you need them.

If you have further questions concerning use of the medicine refer to your doctor or pharma-

4. Side Effects:

As for any medicine, the use of Septadine may cause side effects in some users. Do not be alarmed by the list of side effects. You will probably not suffer from any of them.

Stop treatment and refer to your doctor:

In case of skin sensitivity (rare)

Other Side Effects:

Redness and local irritation.

If one of the side effects becomes more serious, or you suffer from a side effect not mentioned in the insert, consult your doctor.

Reporting Side Effects

You can report side effects to the Ministry of Health through the online form for reporting side effects that you will find on the homepage of the Ministry of Health website: www.health.gov.il

or by entry to the link:

https://forms.gov.il/globaldata/getsequenc e/getsequence.aspx?formType=AdversEff ectMedic@moh.gov.il

5. How to store the medicine?

Avoid poisoning!

This medicine, and all other medicine, must be stored in a safe place out of the reach of children and/or infants, in order to avoid poisoning.

Do not induce vomiting unless explicitly instructed to do so by the doctor.

 Do not use the medicine after the expiry date appearing on the package.

The expiry date refers to the last day of that

- Store in a cool place, below 25°C.
- · Close tightly to prevent entry of air and damp.
- · Warning! Flammable substance, keep away from fire.
- Store in the original package.
- You can use the product after opening until expiry of its validity.

6. Additional information

In addition to the active substances the medicine also contains:

Glycerin, Propylene Glycol, Methylene Blue, Purified water.

Appearance of the medicine and contents of the package:

Blue solution.

Contents: 500 ml, 1000 ml.

Manufacturer and Reg. Owner:

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

This leaflet was inspected and approved by the Ministry of Health on: 31.12.2015 Registration No. of the medicine in the National Drug Register of the Ministry of

Health: 1085829253