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

This medicine is dispensed without a doctor's prescription

Alcosept
Solution

Composition:
Chlorhexidine Gluconate 0.5% w/v
Ethanol 70% w/v
Inactive and allergenic ingredients 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 disinfection of the skin.
Therapeutic class: antiseptics.

2. Before using the medicine

Do not use this medicine:

- If you are sensitive (allergic) to the active ingredients chlorhexidine gluconate and/or ethanol or to any of the other ingredients this medicine contains (see section 6 "Additional information").
- 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).

Special warnings regarding the use of the medicine

- Alcosept 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 Alcosept 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.

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.
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:
Wipe the area intended for disinfection with a cotton wool ball soaked in Alcosept whenever necessary.
If you took an overdose or if a child swallowed this medicine by mistake, go to the doctor or to a hospital emergency room immediately and take 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 Alcosept 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) and allergic reactions (e.g., inflammation of the skin, itch, redness, eczema, rash, hives, skin irritation, blisters).
- Chemical burns may occur in newborns and infants.

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.
- 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, Tartrazine.
What does the medicine look like and what are the contents of the package?
Yellow solution.
The medicine comes in package sizes of: 100 ml, 300 ml, 500 ml or 1,000 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 04/2024 in accordance with the Ministry of Health guidelines.
Registration number of the medicine in the national drug registry of the Ministry of Health:
129-67-30806-00

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