

Patient Leaflet Accordingto the Pharmacists' Regulations (Preparations) - 1986

This medicine is sold without a doctor's prescription

Ipadine 0.5%

Solution

Active ingredients and their concentration: Chlorhexidine Digluconate 0.5% w/v and Isopropanol 70% v/v

For a list of the inactive ingredients and allergens in the medicine – see section 6. Read this entire leaflet carefully before using this medicine.

This leaflet contains concise information about the medicine. If you have any further questions, please refer to your doctor or pharmacist. You must use this medicine properly. Consult the pharmacist if you are in need of additional information.

1. What is the medicine intended for ?

Ipadine 0.5% is a solution intended for use in the following cases: • disinfection of the skin especially prior to performing invasive medical procedures, • disinfection of the umbilicus in neonates.

Therapeutic Group - Antiseptic preparations **2. Before using the medicine**

X Do not use the medicine:

- If you are sensitive (allergic) to the active ingredients or to any of the other ingredients of the medicine (for a list of inactive ingredients, see section 6) "Additional information". Do not use the preparation on brain tissue, the meninges, in the middle ear or on the sex organs.
- Do not use on skin wounds, cracked skin, injured skin, or as a cleaning agent for the skin.
 Use of this preparation does not constitute a substitute for sterile gloves.

Special warnings regarding the use of this medicine:

- If you are sensitive to any type of food or medicine, inform your doctor before the use of this medicine.
 In cases in which swelling develops around the wound, or the wound is accompanied by heat, consult your doctor.
- Use the medicine according to its designated use. Do not use in the eyes; this may cause significant and permanent damage to the eye if it comes into contact and is not rinsed out immediately. Not for oral use and do not swallow.

Not for use in the ear; this may cause deafness in the event it enters the middle ear if the eardrum is perforated. In any of these instances, rinse immediately in cold water. Infants up to one year of age may be more sensitive to the medicine. Pay attention when using the medicine. Avoid contact of the preparation with the eyes, ears and mouth. In the event of contact with these areas — rinse well in cold water. In the event the preparation was used on the scalp, avoid wetting the hair as much as possible. Hair that is wet from the preparation is flammable and drying it will take up to an hour. Avoid prolonged contact of the skin with preparations containing alcohol at a high concentration. Stop using the medicine with the appearance of signs of irritation. See chapter 4 "Side effects".

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

Pregnancy and breastfeeding:

There is no counterindication for use of this medicine if you are pregnant or breastfeeding.

[] Important information about some of the ingredients in this medicine: The preparation contains a type of alcohol known as Isopropanol, also known as Isopropyl Alcohol.

3. How to use the medicine?

Do not light a cigarette or expose to fire until the product is completely dry.

Not for oral use and do not swallow.

For external use only. Check with your doctor or pharmacist if you are not sure of the dosage or manner of treatment with this preparation. Dip a sterile gauze pad and sterilized the desired area. After sterilizing the umbilicus, dry the area using a sterile gauze pad.

If you have accidentally taken a higher dose or if a child or has accidentally swallowed the medicine, refer immediately to the hospital emergency room and bring the package of the medicine with you.

<u>Do not induce vomiting</u> unless explicitly instructed to do so by a doctor.

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

4. Side Effects:

Like any medicine, the use of this preparation may cause side effects in some users. Do not be alarmed while reading the list of side effects, you may not suffer from any of them.

Side effects which require special consideration Allergic reaction or severe allergic reaction, including symptoms such as: difficulty breathing, wheezing, anaphylactic shock, swollen face, urticaria (itchy skin), itchiness and swelling, rash or local inflammation in the skin (rare): stoo treatment and refer to a doctor. Side effects and drug interactions in children and infants: parent must report every side effect as well as every additional medicine given to the child to the attending physician. If side effects appeared, if one of the side effects has exacerbated, of if you suffer from side effects not mentioned in the leaflet, consult with your doctor. Side effects may be reported to the Ministry of Health by clicking on the link "Report on side effects following medicinal treatment" found on the homepage of the Ministry of Health website (www.health.gov.il) which directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il/

5. How to store the medicine?

• Avoid poisoning! This medicine, and any other medicine, must be stored in a safe place out of the sight and reach of children and/or infants, 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) appearing on the package / bottle / carton / label. The expiry date refers to the last day of that same month. • Storage conditions: Store below 25°C, in the original packaging in order to protect against light. After the initial opening of the bottle, it may be used for a period of 3 months, but no later than the expiry date of the preparation.

Caution! Inflammatory substance, keep away from fire. Even according to packaging conditions / recommended storage, medicines are preserved for a limited time only. Please pay attention to the expiry date of the preparation!

In case of any doubt, consult the pharmacist who supplied you with the medicine. Do not store different medicines in the same packaging.

6. Additional information

In addition to the active ingredient/s, the medicine also contains the following inactive ingredients: Purified water, Carmosine (E122; Azorubine). What does the medicine look like and what

does the packaging contain?

 The medicine appears as a slightly pink transparent liquid, having the characteristic odor of alcohol.

 The solution is packaged in an opaque white bottle with a screw cap. There is packaging in which the medicine is supplied with a pump as well. The pump is screwed on instead of the cap.

Not all packaging is marketed.

Packing size: bottle containing 500 ml of solution.

Manufacturer and registration holder:

Ben Shimon Floris Ltd. Private Company number 511126831, Misgav Industrial Park, Mobile Post 2017400.

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