

**Patient package insert according to
Pharmacists' Regulations (Preparations)- 1986**

This medicine can be sold without a physician's prescription

Boric Acid Vitamed, Eye Drops, Solution

Composition:

Boric acid 1.9% W/V.

Each 1 ml contains: 19 mg Boric acid.

Inactive ingredients and allergens in the medicine- see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of this medicine".

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

Use this medicine according to the instructions in section 3 "How to use this medicine?" in this leaflet. Consult the pharmacist if you need additional information. Refer to a doctor if the symptoms of your illness get worse or if they do not improve after 3 days.

1. What is the medicine intended for?

The medicine is intended as a mild antiseptic for the eyes and for the relief of mild eye irritations of the eyes caused by various irritant substances, such as smoke, dust, etc.

Therapeutic group: Anti-infective (Antiseptic).

2. Before using this medicine

Do not use this medicine if:

- You are hypersensitive (allergic) to the active ingredient (Boric acid) or to any of the other ingredients this medicine contains (see section 6 "Additional Information").

Special warnings regarding the use of this medicine

- Refer to your doctor or pharmacist before using **Boric Acid Vitamed**.
- Do not use the medicine while wearing contact lenses (see additional information in section 2 "Important information about some of the ingredients of this medicine").

Children and adolescents:

The medicine is intended for adults and children above 6 years of age. Consult a doctor before use in children under this age.

Drug interactions:

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

Pregnancy and breastfeeding:

No adequate controlled studies have been performed on the use of the medicine in pregnant or breastfeeding women.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult a doctor or pharmacist before using the medicine.

Driving and using machines:

As with all eye drops, your vision may be blurred after use. Wait until your vision is clear before driving or using machines.

Important information about some of the ingredients of this medicine

The medicine contains Benzalkonium Chloride, which could be absorbed by soft contact lenses and change their color. Remove contact lenses before using the medicine and reinsert them after 15 minutes from the time of use.

Benzalkonium Chloride may also cause eye irritation, especially if you suffer from dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel an abnormal eye sensation, stinging, or pain in the eye after using this medicine, refer to your doctor.

This medicine contains 0.1 mg of Benzalkonium Chloride in each 1 ml, which is equivalent to 0.1 mg/ml.

3. How to use this medicine?

Check with the doctor or pharmacist if you are not sure about the dosage and manner of treatment with the medicine.

Unless otherwise directed by a doctor, the dosage generally used for adults and children over the age of 6 is: to rinse the eye, as needed.

If your condition does not improve within 3 days, stop the treatment and contact a doctor.

Do not exceed the recommended dose.

Method of administration:

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

Instructions for use:

1. Wash your hands thoroughly before using the eye drops.
2. Tilt back your head or lie down on a bed and with the aid of a finger, pull the lower eyelid away slightly from the eye and create a gap.
3. Instill the medicine into the gap and close your eyes for 1-2 minutes and do not blink.
4. To prevent contamination of the solution, make sure that the dropper tip does not come into contact with any surface, including your finger and eye, and close the bottle tightly after use.

If you have accidentally taken a higher dosage

If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or 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 each time you take a medicine. Wear glasses if you need them.

If you have further questions on the use of this medicine, consult the doctor or pharmacist.

4. Side effects

As with any medicine, the use of **Boric Acid Vitamed** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Eye drops containing Benzalkonium Chloride may cause eye irritation, especially in patients who suffer from dry eyes or corneal disorders.

For more information, see section 2-"Important information about some of the ingredients of this medicine".

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

Report of side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report adverse effects and problems associated with medications and drugs" on the Ministry of Health home page (www.health.gov.il), which links to an online form for reporting side effects, or by following 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 closed place out of the reach and sight of children and/ or infants 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 (exp. Date) that appears on the package. The expiry date refers to the last day of that month.

• Storage conditions:

- Store below 25°C.
- The medicine can be used for up to 30 days after the bottle is first opened and not later than the expiry date, that appears on the package.
- Keep the bottle tightly closed.
- Do not use this medicine if the color of the solution has changed or if it has become cloudy.

- Do not throw away any medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains:

Benzalkonium Chloride 50% Solution, Disodium Edetate, Sodium Hydroxide/ Hydrochloric Acid, Purified Water.

What the medicine looks like and what the package contains:

A bottle containing a clear, colorless solution, practically free from particles.

Approved package size: 10 ml.

Manufacturer and registration holder: Vitamed Pharmaceutical Industries Ltd., 6 Hatahana St., P.O.B. 114, Binyamina 3055002, Israel.

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Drug registration number at the national drug registry of the Ministry of Health: 123-85-28639-00