

PATIENT INFORMATION LEAFLET
BORIC ACID EAR DROPS, BORIC ACID 1.83% w/v

BORIC ACID EAR DROPS, BORIC ACID 1.83% w/v

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, health care provider or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist.

In this leaflet:

- a) What BORIC ACID EAR DROPS is and what it is used for
- b) Before you use BORIC ACID EAR DROPS
- c) How to use BORIC ACID EAR DROPS
- d) Possible side effects
- e) How to store BORIC ACID EAR DROPS
- f) Further information

a) WHAT BORIC ACID EAR DROPS IS AND WHAT IT IS USED FOR

BORIC ACID EAR DROPS is an anti-infective otic solution used for the treatment of ear otitis and superficial infections of the external auditory canal caused by organisms susceptible to the action of the antimicrobe.

b) BEFORE YOU USE BORIC ACID EAR DROPS

DO NOT use BORIC ACID EAR DROPS:

- If you are allergic to boric acid, or any of the other ingredients of this medicine.
- Do not use if you have a perforated tympanic membrane

Take special care

Talk to your doctor or nurse before receiving BORIC ACID EAR DROPS.

- If you experience an allergic reaction to BORIC ACID EAR DROPS.

PATIENT INFORMATION LEAFLET
BORIC ACID EAR DROPS, BORIC ACID 1.83% w/v

- Allergic reactions occur uncommonly and serious reactions occur rarely. If you experience any allergic (hypersensitivity) reaction or any side effect please refer to section (d).
- Avoid spreading of solution on mucous membranes and the damaged surface of skin.
- Treatment with boric acid should not be continued for more than seven days in the absence of any clinical improvement, since prolonged use may lead to skin sensitization and the emergence of resistant organisms.

Other medicines and BORIC ACID EAR DROPS

Tell your doctor or nurse if you are taking or have recently taken, or might take any other medicines, including medicines obtained without a prescription. ABBORI Ear drops may interact with the following drugs and products;

- Carboxymethylcellulose
- Septrafilm
- Sodium hyaluronate
- Riboflavin
- Dextranomer
- Hyaluronan

Pregnancy and breast feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Effects on ability to drive and use machines

None known.

c) How to use BORIC ACID EAR DROPS

- Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- The recommended dose is three or four drops to be instilled into the affected ear, with the head inclined, preferably lying down or as directed by the physician.
- BORIC ACID EAR DROPS should only be used in children if considered essential by the physician, in patients

PATIENT INFORMATION LEAFLET
BORIC ACID EAR DROPS, BORIC ACID 1.83% w/v

Instructions for use

You must not use the bottle if the tamper-proof seal on the bottle neck is broken before you first use it.

Using the drops for the first time: These eye drops come in a bottle with a coned shaped nozzle and screw cap. The inside of the screw cap contains a spike. The screw cap is fitted to the bottle in such a way that there is no contact between the spike and the top of the nozzle of the bottle. In order to open the bottle, it is necessary to tighten the screw cap further, so that the edge of the screw cap and the nozzle edge are totally aligned. At this point the screw cap spike will pierce the top of the nozzle of the bottle, which will open the bottle. Once the bottle has been opened in this way, unscrew the screw cap fully to remove it from the bottle and apply the ear drops.

To avoid contamination, do not touch or allow the dropper tip touch the ear, areas around the ear or any surface. It may become contaminated with bacteria that can cause infections.

d) Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The main symptoms of acute Boric acid are vomiting, diarrhea, abdominal pain, an erythematous rash involving both skin and mucous membranes, followed by desquamation, and stimulation or depression of the central nervous system. There may be renal tubular damage, convulsions and hyperpyrexia.

Long-term usage of preparation may also cause disfunction of kidneys.

How to store BORIC ACID EAR DROPS

Use as directed by physician. Keep out of reach of children.

Do not store above 30°C and protect from excessive heat and freezing

PATIENT INFORMATION LEAFLET
BORIC ACID EAR DROPS, BORIC ACID 1.83% w/v

Do not use after the expiry date which is stated on the bottle after “Expiry”. The expiry date refers to the last day of that month.

Throw the bottle away 28 days after opening, even if there is solution remaining.

Do not use BORIC ACID EAR DROPS if you notice the tamper-proof seal is broken.

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

e) Further information

What BORIC ACID EAR DROPS contains

The **active** substance is Boric Acid.

The **other** ingredients are Benzalkonium Chloride, Borax, Propylene Glycol and water for injection.

What BORIC ACID EAR DROPS looks like and the contents of the pack

BORIC ACID EAR DROPS is a clear, colorless solution practically free from particles supplied in either a 5 ml or 10 ml clear colorless low density polyethylene (LDPE) container.

Marketing authorisation holder and manufacturer

Abacus Parenteral Drugs Limited

Block 191, Plot no.114, Kinga Mukono

P. O. Box 31376, Kampala, Uganda.

Phone: +256-312 380 800

Fax: +256-312 380 820

Email: apdl@abacuspharma.com

For any information about this medicinal product, please contact the local representative of the supplier:

Name: Gihanda John Davis

Address: Kigali City Market, B1-R85, Kigali, Rwanda

Tel: +250 788218527

e-mail: aplrw.pharmacist@abacuspharma.com

This leaflet was last revised in APRIL/2023.