1. Name of the Medicinal Product

Boric acid Ear Drops

2. Qualitative and Quantitative Composition

Each 1ml of solution contains Boric acid B.P equivalent to Boric acid 1.83%w/v

3. Pharmaceutical Form

Otic solution

4. Clinical Particulars

4.1 Therapeutic Indications

Boric acid Ear Drops is indicated for the treatment of ear otitis and superficial infections of the external auditory canal caused by organisms susceptible to the action of the anti-microbe.

4.2 Posology and Method of Administration

Adults, Elderly and children.

Three or four drops to be instilled into the effected ear, with the head inclined, preferably lying down or as directed by the physician.

Infants

Only use if considered essential by the physician.

4.3 Contraindications

Hypersensitivity to Boric acid or any of the ingredients, perforated tympanic membrane.

4.4 Special Warnings and Precautions for Use

Try to avoid spreading of solution on mucous membranes and the damaged surface of a 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.

4.5 Interaction with other medicinal products and other forms of interaction

When using other drugs or over the counter products at the same time, the effects of Boric acid ear drops may change. This may increase your risk for side-effects or cause your drug not to work properly. Tell your doctor about all the drugs, vitamins, and herbal supplements you are using, so that your doctor can help you prevent or manage drug interactions. ABBORI Ear drops may interact with the following drugs and products;

- Carboxymethylcellulose
- Dextranomer
- Hyaluronan
- Riboflavin
- Seprafilm
- Sodium hyaluronate

4.6 Pregnancy and lactation

Use of boric acid ear drops during pregnancy and lactation period should be based on the physician advice.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

The main symptoms of acute Boric acid 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.

4.9 Overdose

Treatment of poisoning is symptomatic. The stomach should be emptied if a large amount of Boric acid has been ingested; activated charcoal is not effective. Peritoneal dialysis or haemodialysis may be of value.

5. Pharmacological Properties

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: Otologicals; Anti-infectives

ATC code: S02AA03

Information regarding the mechanism of action of boric acid in mediating its antibacterial or antifungal actions is limited. Boric acid inhibits biofilm formation and hyphal

transformation of Candida albicans, which are critical virulence factors. In addition, arrest of fungal growth was observed with the treatment of boric acid.

5.2 Pharmacokinetic properties

Absorption

Boric acid is well absorbed from the gastrointestinal tract, open wounds, and serous cavities but displays limited absorption in intact skin. Following intraperitoneal injection in mice, the peak concentration was reached in about 1.0-1.5 hr in the brain whereas the value was 0.5 hr in other tissues.

Volume of distribution

Volume of distribution ranges from 0.17 to 0.5 L/kg in humans, where large amounts of boric acid are localized in brain, liver, and kidney.

Route of elimination

Regardless the route of administration, boric acid predominantly undergoes rapid renal excretion of >90% of total administered dose as unchanged form. Small amounts are also excreted into sweat, saliva, and feces. Following administration as ointment, urinary excretion of boric acid accounted for only 1% of the administered dose.

Half life

According to human cases of poisoning, the elimination half-life of boric acid ranges from 13 to 24 hours.

Clearance

A case report of acute boric acid poisoning following oral ingestion of 21 g of boric acid presents the total body clearance of 0.99 L/h before hemodialysis.

Toxicity

Acute oral LD50 is 2660 mg/kg in rat [MSDS]. Individuals are likely to be exposed to boric acid from industrial manufacturing or processing. Local tissue injury from boric acid exposure is likely due to caustic effects. Systemic effects from boric acid poisoning usually occur from multiple exposures over a period of days and involve gastrointestinal, dermal, CNS, and renal manifestations. Gastrointestinal toxicity include persistent nausea, vomiting, diarrhea, epigastric pain, hematemesis, and blue-green discoloration of the feces and vomit. Following the onset of GI symptoms, a characteristic intense generalized erythroderma follows. Management of mild to moderate toxicity should be supportive. In case of severe toxicity, dialysis may be required in addition to supportive treatment

6. Pharmaceutical Particulars

6.1 List of Excipients

- Benzalkonium Chloride B.P
- Borax B.P

- Propylene glycol B.P
- Water for injection as the vehicle B.P

6.2 Incompatibilities

None Known

6.3 Shelf life

36 months

6.4 Special precautions for storage

Do not store above 30°C and do not freeze.

6.5 Nature and contents of container

10ml sealed transparent low density polyethylene plastic ampoules, packed in mono baby cartons

6.6 Special precautions for disposal and other handling

Use as directed by physician.

Keep out of reach of children.

7. **Marketing Authorisation Holder**

   Abacus Parenteral Drugs Ltd. Uganda.
   Block 191, Plot No.114, Kinga Mukono
   P.O.Box 31376, Kampala, Uganda.

8. **Marketing Authorisation Number(s)**

   N/A

9. **Date of first authorisation/renewal of the authorisation**

   N/A

10. **Date of revision of the text**

    24/08/2018