



Borox



- Hygiene of ear cavity
- Prevention of ear canal
- Removal of ear wax excess
- Irritation and inflammation

Medical Device **CE**



MADE IN ITALY

EARACHE

DESCRIPTION

Borox is indicated for ear care hygiene and useful to remove ear wax excess and in the prevention of irritation and inflammation of the ear canal.



Spray: 2-3 sprays per ear canal. It can be used several times daily.

Ear Drops: Adults: 3-4 drops per ear canal twice a day. **Childs:** 1-2 drops per ear canal twice a day.

THERAPEUTIC INDICATIONS

- Wax excess
- Inflammation (redness and swelling) of the external ear canal
- Recurring ear infection
- In case of increased risk of infection
 - Exposure in swimming pools
 - Open-air showers (e.g. at sea place)
 - Exposure at wind and at climate change

PRESENTATION

Borox is available in two format:

Borox Spray: 50ml glass bottle provided with auricular spray

Borox Ear Drops: 10ml glass bottle provided with dropper, more suitable for infants and children.

INGREDIENTS

Aqua, glycerin, propylene glycol, lactic acid, boric acid, sodium docusate, sodium chloride, potassium sorbate, EDTA, sodium benzoate, chamomilla recutita flower water, polysorbate 20, sorbitan oleate.*

*only in Borox Ear Drop version

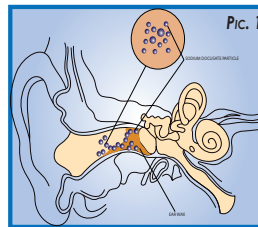
REGULATORY STATUS

- Class I*
- Free sale certificate
- Certificate of origin (at the time of invoicing)
- Declaration of conformity
- ISO 13485 certificate
- US FDA registration

* The product will be certified in class IIa within May 2020

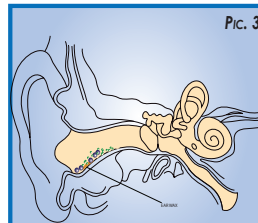
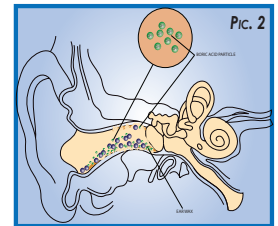


Borox pH 3.5	✓	Rebalance the pH of the external auditory canal (EAC)
3% Boric Acid + Ascorbic Acid	✓	Defend against bacterial and fungal proliferation
SODIUM DOCUSATE	✓	Hygiene of the ear canal
Linear hydroglyceric jet with calibrated pressure	✓	Removal of earwax excess
Glycol-glycerin solution	✓	Low free water content



The amphipathic property of **SODIUM DOCUSATE** capable to emulsify the earwax and to facilitate its removal.

BORIC ACID, thanks to its acidity, reduces the risk of bacterial and fungal growth cause of irritation and inflammation.



The cleaning action of **HYDROGLICERIC SOLUTION** facilitates the removal of earwax.

CLINICAL TEST

- **RISK ANALYSIS** - according to UNI CEI EN ISO 14971
- **BIOCOMPATIBILITY** - according to UNI EN ISO 10993:
- SKIN IRRITATION TEST - according to ISO 10993-10:2010
- CYTOTOXICITY for DIRECT CONTACT - according to ISO 10993-5:2009
- **CLINICAL EVALUATION** - according to MEDDEV 2.7-1
- **STABILITY** - according to ICH Guidelines:
- ACCELERATED STABILITY STUDY
- LONG TERM