



1. Composition

Paradichlorobenzene	2%w/v
Benzocaine	2.7%w/v
Chlorbutol	5%w/v
Turpentine oil	15% w/v

In oily base containing olive oil.

2. Dosage form and strength

Otiflox WX Ear Drops are available in 10ml bottle with dropper.

3. Clinical particulars

3.1 Therapeutic indication

Otiflox WX Ear Drops is indicated in patient of impacted ear wax and keratosis.

3.2 Posology and method of administration

Instil 2-3 drops of Otiflox WX Ear Drops in affected ear 3-4 times a day or as directed by physician.

3.3 Contraindication

Contraindicated in patients with hypersensitivity for any of ingredient of formulation and for long term use.

3.4 Special warnings and precautions for use

Before using this medication, tell your doctor or pharmacist your medical history, especially of: hearing problems (including deafness, decreased hearing), intestinal problems (including blockage, swelling, ulcers), kidney problems, myasthenia gravis, Parkinson's disease.

3.5 Drug interactions

No specific drug interactions noted.

3.6 Use in special population

- Pediatric: Safe in children from 1 year and above.

- Geriatric: Use with caution.
- Liver impairment: Use with caution.
- Renal failure: Use with caution.
- Pregnancy and lactation: Use with caution.

3.7 Effects on ability to drive and use machine

Patients should be cautioned against engaging in activities requiring complete mental alertness, and motor coordination such as operating machinery until their response to Otiflox WX Ear Drops is known.

3.8 Undesirable effects

- Sleeplessness
- Anaphylaxis
- Headache

3.9 Overdose

There is limited experience of overdose with Otiflox WX ear Drops. Initiate general symptomatic and supportive measures in all cases of overdosages where necessary.

4. Pharmacological properties

4.1 Mechanism of action

Paradichlorobenzene is a chlorinated aromatic hydrocarbon that helps remove ear wax. It reduces the thickness of the ear-wax. Acts as a hydrating agent.

Chlorbutol acts as a wax softener.

Turpentine oil acts as Lubricating agent

Benzocaine acts as a local anaesthetic

Olive oil-Base

- Olive oil can also be used to help prevent the build-up of earwax.
- According to American Academy of Family Physicians, Olive oil is considered best for the purpose of wax removal.
- As per British National Formulary, all the available wax softeners should have Olive oil as the base.
- Compared to Arachis oil, which is used mostly in ear preparations, Olive oil is 96 % more effective as compared to Arachis oil which is just 91% effective.

4.2 Pharmacodynamic properties



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Benzocaine is a local anesthetic commonly used as a topical pain reliever. It is the active ingredient in many over-the-counter analgesic ointments. It is also indicated for general use as a lubricant and topical anesthetic on intratracheal catheters and pharyngeal and nasal airways to obtund the pharyngeal and tracheal reflexes; on nasogastric and endoscopic tubes; urinary catheters; laryngoscopes; proctoscopes; sigmoidoscopes and vaginal specula.

Turpentine oil, when inhaled, may help reduce congestion. When used on the skin, turpentine oil may cause warmth and redness that can help relieve pain in the tissue underneath.

4.3 Pharmacokinetic properties

Not available.

5. Nonclinical properties

5.1 Animal Toxicology or Pharmacology

Not required.

6. Description

Already mentioned and covered in the above points.

7. Pharmaceutical particulars

7.1 Incompatibilities

There are no known incompatibilities.

7.2 Shelf-life

36 months.

7.3 Storage and handling instructions

Store in a dry, well-ventilated place at a temperature not exceeding 30°C. Do not freeze.



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