



1. Generic Names

Paradichlorobenzene

Benzocaine

Chlorbutol

Turpentine oil

2. Qualitative and Quantitative 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.

3. Dosage form and strength

Topical ear drops containing Paradichlorobenzene 2%, Benzocaine 2.7%, Chlorbutol 5%, Turpentine oil 15%.

4. Clinical particulars

4.1 Therapeutic indication

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

4.2 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.

4.3 Contraindication

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

4.4 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.

4.5 Drug interactions

No specific drug interactions noted.

4.6 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.

4.7 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.

4.8 Undesirable effects

- Sleeplessness
- Anaphylaxis
- Headache

4.9 Overdose



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

5. Pharmacological properties

5.1 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.

5.2 Pharmacodynamic properties

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.

5.3 Pharmacokinetic properties

Not available.

6. Nonclinical properties

6.1 Animal Toxicology or Pharmacology

NA.

7. Description

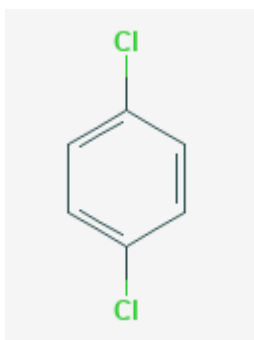
Paradichlorobenzene is a synthetic, white crystalline solid that is practically insoluble in water and soluble in ether, chloroform, carbon disulfide, benzene, alcohol and acetone.

Chemical name: 1,4-dichlorobenzene

Molecular formula: $C_6H_4Cl_2$

Molecular weight: 147 g/mol

Structure:



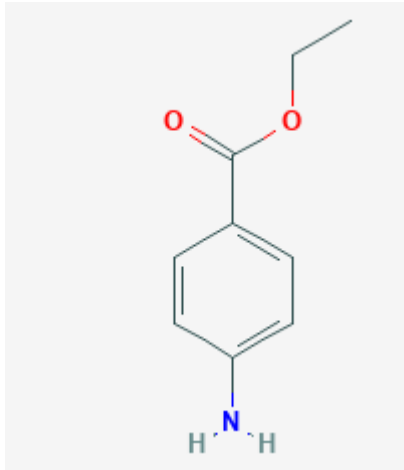
Benzocaine is an ester of paraaminobenzoic acid, lacking the terminal diethylamino group of procaine, with anesthetic activity.

Chemical name: ethyl 4-aminobenzoate

Molecular formula: $C_9H_{11}NO_2$

Molecular weight: 165.19 g/mol

Structure:



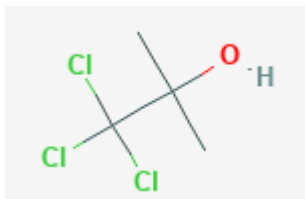
Chlorbutol is an alcohol-based preservative with no surfactant activity. It also elicits sedative-hypnotic and weak local anesthetic actions in addition to antibacterial and antifungal properties.

Chemical name: 1,1,1-trichloro-2-methylpropan-2-ol

Molecular formula: $C_4H_7Cl_3O$

Molecular weight: 177.45 g/mol

Structure:



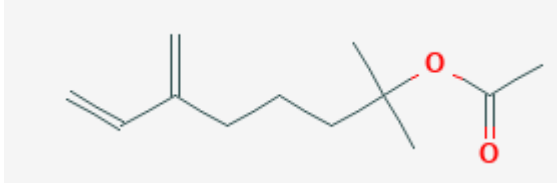
Turpentine oil

Chemical name: (2-methyl-6-methylideneoct-7-en-2-yl) acetate

Molecular formula: $C_{12}H_{20}O_2$

Molecular weight: 196.29 g/mol

Structure:



8. Pharmaceutical particulars

8.1 Incompatibilities

There are no known incompatibilities.

8.2 Shelf-life

36 months.

8.3 Packaging Information

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

8.4 Storage and handling instructions

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

9. Patient Counselling Information

9.1 Adverse Reactions

Refer part 4.8

9.2 Drug Interactions

Refer part 4.5

9.3 Dosage

Refer part 4.2

9.4 Storage

Refer part 8.4

9.5 Risk Factors

Refer part 4.4



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9.6 Self-monitoring information

NA

9.7 Information on when to contact a health care provider or seek emergency help

Patient is advised to be alert for the emergence or worsening of the adverse reactions and contact the prescribing physician.

9.8 Contraindications

Refer part 4.3

10. Manufactured by SELVOK PHARMACEUTICAL CO.

11. Details of permission or license number with date

12. Date of revision: January 2021



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