

Waxodiz™

Ear drops

1. Generic Name

Paradichlorobenzene, Benzocaine, Chlorbutol, Turpentine oil.

2. Qualitative and Quantitative Composition

Paradichlorobenzene 2% w/v

Benzocaine IP 2.7% w/v

Chlorbutol IP 5% w/v

Turpentine Oil BP..... 15% w/v

Oil base q.s

3. Dosage form and strength

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

4. Clinical particulars

4.1 Therapeutic indication

Waxodiz Ear Drops are indicated as an aid in the removal of impacted ear wax.

4.2 Posology and method of administration

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

4.3 Contraindication

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

4.4 Special warnings and precautions for use

Caution should be observed while prescribing Waxodiz Ear drops to patients with medical history, especially of: hearing problems (including deafness, decreased hearing, perforated eardrum).

FOR EXTERNAL USE ONLY. NOT FOR INJECTION

4.5 Drug interactions

None known.

4.6 Use in special population

- Pediatric: Safety and efficacy has not been evaluated in children.
- Geriatric: Use with caution.
- Liver impairment: Use with caution.
- Renal failure: Use with caution.
- Pregnancy and lactation: During pregnancy, Waxodiz ear drops should be used only when clearly needed. It is unknown if this medication passes into breast milk. Consult doctor before breast-feeding

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 Waxodiz Ear drops is known.

4.8 Undesirable effects

- Ear pain and irritation on instillation
- Sleeplessness
- Anaphylaxis
- Headache

4.9 Overdose

There is limited experience of overdose with Waxodiz Ear drops. Initiate general symptomatic and supportive measures in all cases of overdosages where necessary.

5. Pharmacological properties

5.1 Mechanism of action

Paradichlorobenzene reduces the thickness of the ear-wax. It works by hydrating the desquamated sheets of keratinocytes and by inducing keratolysis, causing disintegration of the cerumen (ear wax).

Benzocaine acts as a local anaesthetic. It binds to sodium channels and reversibly stabilizes the neuronal membrane which decreases its permeability to sodium ions. Depolarization of the neuronal membrane is inhibited thereby blocking the initiation and conduction of nerve impulses.

Chlorbutol acts as a wax softener.

Turpentine oil acts as lubricating agent, making it easier to dislodge and remove the impacted ear wax.

5.2 Pharmacodynamic properties

The drug is applied topically to aid the removal of cerumen. Thus, normal pharmacological criteria cannot be applied.

The action is thought to be due to the loosening and lubricating properties of the solvent mixture, rather than its solvent properties. This is intrinsic to the solvent mixture.

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

Benzocaine is a local anaesthetic commonly used as a topical pain reliever.

Chlorbutol acts as a wax softener.

Turpentine oil is an oily substance to aid lubrication of the cerumen plug. (Water based solvents cause swelling of cerumen).

5.3 Pharmacokinetic properties

Not available.

6. Nonclinical properties

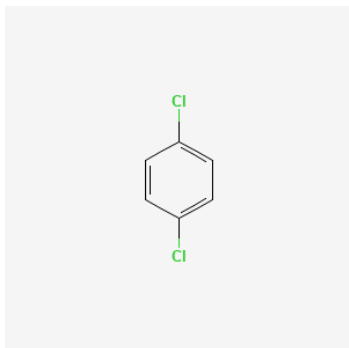
6.1 Animal Toxicology or Pharmacology

NA.

7. Description

Paradichlorobenzene is classified as a ceruminolytic agent. Ceruminolytic agents are substances that soften and dissolve earwax, making it easier to remove.

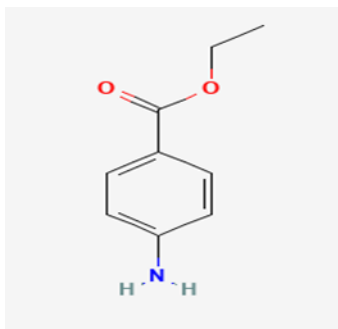
Its chemical name is 1,4-dichlorobenzene and its structural formula is



Its empirical formula is $C_6H_4Cl_2$, and its molecular weight is 147.00 g/mol.

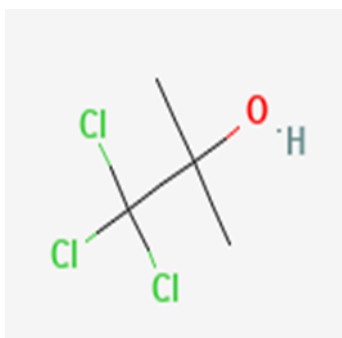
Benzocaine is classified as an ester local anaesthetic, specifically a topical local anaesthetic.

Its chemical name is ethyl 4-aminobenzoate and its structural formula is



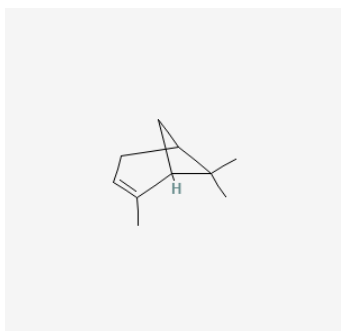
Its empirical formula is $C_9H_{11}NO_2$, and its molecular weight is 165.19 g/mol.

Chlorbutol: Its chemical name is 1,1,1-trichloro-2-methylpropan-2-ol and its structural formula is



Its empirical formula is $C_4H_7Cl_3O$, and its molecular weight is 177.45 g/mol

Turpentine oil: The chemical name for the main component of turpentine oil, α -pinene, is 2,6,6-trimethylbicyclo [3.1.1] hept-2-ene and its structural formula is



Its empirical formula is $C_{10}H_{16}$ (approx.) and its molecular weight is 136.23 g/mol

8. Pharmaceutical particulars

8.1 Incompatibilities

There are no known incompatibilities.

8.2 Shelf-life

24 months.

8.3 Packaging Information

Waxodiz Ear drops are available in 10ml bottle with dropper.

8.4 Storage and handling instructions

Store below 25°C. Protect from light and moisture. Keep all medicined out of reach of children. Use the solution within one month after opening the container.

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

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:

OM SAI PHARMA PACK. Plot No. 38, 39. Sector -11, I.I.E., SIDCUL, Haridwar, Uttarakhand-249 403, India

11. Details of permission or license number with date: 58/UA/2018

12. Date of revision: May 2025