

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

Sodium bicarbonate 5% w/v ear drops solution
Waxfree

2. Qualitative and quantitative composition

Each dropper bottle contains 10 mL of solution.
Each mL of solution contains 50 mg of sodium bicarbonate.

For a full list of excipients, see section 6.1.

3. Pharmaceutical form

Ear drops solution.

Clear, colourless solution.

4. Clinical particulars

4.1 Therapeutic indications

Sodium bicarbonate is indicated for the removal of ear wax.

4.2 Posology and method of administration

Route of administration

For auricular use only.

Instil 3 - 4 drops twice daily, for up to 7 days.

If the ear wax is hard and impacted, the drops can be used twice daily for several days and this may reduce the need for mechanical removal of the wax. The patient should lie with the affected ear uppermost for 5 to 10 minutes after the drops are introduced into the ear.

4.3 Contraindications

Waxfree is contraindicated in patients with

- a history of hypersensitivity to sodium bicarbonate or any excipients listed in section 6-1.
- perforated eardrums, inflammation, recent ear surgery, injury or infection.
- a mastoid cavity.

4.4 Special warnings and precautions for use

Never attempt to remove the softened wax by pushing a cotton swab into the ear canal, it may shove the wax farther back into the canal, which could lead to an ear infection or a perforated ear drum.

Use the lowest dose and shortest duration of therapy appropriate to the condition being treated.

4.5 Interaction with other medicinal products and other forms of interaction

No known drug interaction has been reported.

4.6 Pregnancy and lactation

No adverse effects during pregnancy and/or lactation were reported.

4.7 Effects on the ability to drive and use machines

No studies on the effect on the ability to drive and use machines have been performed.

4.8 Undesirable effects

Sodium bicarbonate may cause transient irritation, dryness of the ear canal, redness or rash.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the e-PV desktop applications (https://drive.google.com/file/d/16hwTz0587ZWtSWadbBAMwQPOD_KSExZP/view) or search for e-PV Mobile applications on the Google Play or Apple App Store.

4.9 Overdose

In the case of accidental ingestion, symptomatic therapy is recommended.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacological classification: 20.1.4 Wax removers.

Sodium bicarbonate ear drops are effective in softening the ear wax and facilitating easy extraction of ear wax. The action is thought to be due to the loosening and lubricating properties of the solvent mixture. Sodium bicarbonate ear drops gently soften ear wax before removal. This reduces the need for wax to be physically removed but also makes ear irrigation easier when removal is necessary.

5.2 Pharmacokinetic properties

No pharmacokinetic data for sodium bicarbonate ear drops is available.

5.3 Preclinical safety data

Not applicable.

6. Pharmaceutical particulars

6.1 List of excipients

Glycerol
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 30°C.

6.5 Nature and contents of the container

A sterile, opaque plastic dropper bottle, with a nozzle and a white plastic cap.

Fill volume: 10 ml.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. APPLICANT

Lincoln Pharmaceuticals Limited
Lincoln House, Behind Satyam Complex, Science City Road, Sola
Ahmedabad – 380060
Gujarat
India

8. MANUFACTURER

Lincoln Parenteral Limited
11, Trimul Estate, Khatraj, Tal. Kalol
Dist. Gandhinagar
Gujarat
India

9. REGISTRATION DETAILS

Zimbabwe registration number: 2023/20.1.4/6428
Zimbabwe category for distribution: Pharmacy Medicines (P.)

10. DATE OF REVISION OF THE TEXT

October 2023