## 1. Name of the medicinal Product

Waxfree (Sodium Bicarbonate 5% w/v) Ear Drops BP

## 2. Qualitative and Quantitative Composition

### 2.1 Qualitative declaration

Sodium Bicarbonate BP 5 % w/v

### 2.2 Quantitative declaration

For a full list of excipients, see section 6.1.

## 3. Pharmaceutical Form

Auricular Solution

A clear colourless solution.

## 4. Clinical Particulars

### Therapeutic Indications

Sodium Bicarbonate Ear Drops BP 5% w/v is indicated for the removal of ear wax.

### 4.1 Posology and Method of Administration

*Route of administration:* For auricular use only.

Use 3 to 4 drops into the affected ear(s) 3 to 4 times a day for 3 to 5 days. Allow the drops to warm to room temperature.

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.

Patient should lie with the affected ear uppermost for 5 to 10 minutes after the drops are introduced into the ear.

## 4.2 Contraindications

In patient with known hypersensitivity to Sodium Bicarbonate or to any of excipients. In patient with perforated ear drum, inflammation. Oleax, recent ear surgery, injury or infection. Mastoid cavity.

## 4.3 Special Warnings and Special 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 ear infection or a perforated eardrum. If symptoms do not improve, consult with the physician. Use lowest dose and shortest duration of therapy appropriate to the condition being treated.

**Pregnancy & Lactation:** No adverse effects during pregnancy &/or lactation was reported.

## 4.4 Interaction with other medicinal products and other forms of interaction

No known drug interaction has been reported.

## 4.5 Pregnancy and Lactation

No adverse effects during pregnancy &/or lactation was reported.

## 4.6 Effects on ability To Drive and use Machines

Not applicable

## 4.7 Undesirable Effects

Sodium Bicarbonate Ear Drops BP 5% w/v may cause transient irritation, dryness of the ear canal, redness or rash.

## 4.8 Overdose

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

## 5. Pharmacological Properties

### Pharmacodynamics Properties

Sodium bicarbonate ear drops are effective in softening the ear wax & facilitates 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 prior to removal. This reduces the need for wax to be physically removed, bur also makes ear irrigation easier when removal is necessary.

### 5.1 Pharmacokinetic Properties

No pharmacokinetic data for Sodium bicarbonate ear drops has been available.

### 5.2 Preclinical Safety Data

Not Applicable

## 6. Pharmaceutical Particulars

### List of Excipients

Glycerol (Glycerin) BP

Purified water BP

### Incompatibilities

Not Applicable

### Shelf Life

36 months from the date of manufacture.

### Special Precautions for Storage

Do not store above 30° C. Protect from light. Do not freeze.

**Nature and Contents of Container**

A clear colourless solution filled in a 10 ml Sterile Non-Transparent plastic dropper bottle with white plastic nozzle and plastic cap. Such one labeled bottle is packed in a Printed carton with packing insert.

**Special precaution for disposal and other handling**

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

## 7. Marketing Authorization Holder And Manufacturing Site Addresses

**Name and Address of Marketing Authorization Holder**

Lincoln Pharmaceuticals Limited
Trimul Estate, Khatraj, Taluka: Kalol,
District: Gandhinagar Gujarat, India.
Telephone no.: +91-02764-665000
Fax: +91-02764-281809
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Website: www.lincolnpharma.com

**Name and Address of manufacturing site(s)**

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Telephone no.: +91-02764-665000
Fax: +91-02764-281809
Email: info@lincolnpharma.com
Website: www.lincolnpharma.com

**8. Marketing Authorization Number**

**TAN 21 HM 0294**

**9. Date of First <Registration> / Renewal of The <Registration>**

**20th August, 2021**

10. **Date of Revision of the Text**

**11. Dosimetry (If Applicable)**

Not Applicale

**12. Instructions for preparation of radiopharmaceuticals (if Applicable)**

Not Applicable