

WaxnilTM

Sodium Bicarbonate BP 5% w/v



COMPOSITION

WaxnilTM Ear Drops: Each ml contains Sodium Bicarbonate BP 50 mg.

PHARMACOLOGY

Ear wax which often obstructs the external auditory meatus of the ear contains less than 50% of fatty matter derived from secretions of the sebaceous ceruminous glands. The majority of the wax consists of desquamated epithelium, foreign matter and shed hairs. This non-fatty material forms a matrix holding together the granules of fatty matter to form the ceruminous mass. The addition of oils or solvents binds the mass more firmly together, but aqueous solutions, if they are able to penetrate the matrix, cause a disintegration of the ceruminous mass. Sodium bicarbonate ear drops actively dissolves the wax rapidly by penetrating the dry matrix of the ceruminous mass, reducing the solid ear wax to a Semi-Solid debris. It is a quicker, more effective method for wax removal.

INDICATIONS

WaxnilTM Ear drops is indicated as an aid to soften and in the removal of hardened ear wax from the ear canal.

DOSAGE & ADMINISTRATION

Adults and Children (from 1 year):

1

Tilt the head and gently squeeze 3 to 4 drops into the affected ear without touching the ear with the end of the dropper.

2

Keep head tilted, allow the solution to remain in ear for 5-10 minutes, wipe any surplus with a tissue. Repeat in the other ear if necessary.

3

1-2 APPLICATIONS

Perform 1-2 times daily for up to 5 days.

INSTRUCTION TO USE

To apply, tilt head to one side so that the ear is facing up. Then gently pull the ear lobe up & backward in case of adults and children older than 3 years.

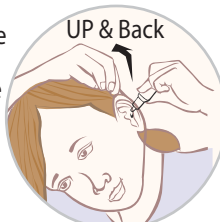


Figure 1: Adult application

In case of pediatric patients gently pull the ear lobe down & backward.

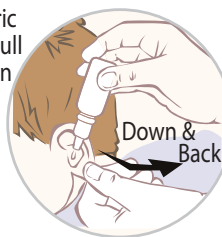


Figure 2: Pediatric application

DRUG INTERACTION

Interaction with other medicinal products and other forms of interaction: Unknown.

CONTRAINDICATIONS

Sodium bicarbonate is contraindicated in patients with perforation of the eardrum or inflammation of the ear or recently have any ear surgery. It is also contraindicated in patients with known allergic reaction to Sodium bicarbonate or any other ingredients of the ear drops.

SIDE EFFECTS

Sodium bicarbonate ear drops can sometimes cause dryness in the ear canal, but this is rarely troublesome. It is unlikely that one will experience any other side-effects but should consult with doctor if there is anything that concerns.

PREGNANCY & LACTATION

Sodium Bicarbonate ear drops can be used during pregnancy and while breast-feeding. The ingredients have been in widespread use for many years, without reports of problems. However, safety trials have not been conducted.

PRECAUTIONS & WARNINGS

- Patients with known allergic (hypersensitive) reactions to Sodium Bicarbonate or any of the ingredients
- Patients with history of ear problems or ear drum is (or has been) damaged.

OVERDOSE

Do not worry if the used too much. Simply wipe away any surplus running from the ear with a tissue.

STORAGE

Protect from light, store below 30°C. Keep away from the reach of the children.

HOW SUPPLIED

WaxnilTM Ear Drops: Each Plastic dropper bottle contains 10 ml of Sodium Bicarbonate otic solution.

Manufactured by



SQUARE
PHARMACEUTICALS LTD.
BANGLADESH