

NDA 11-340/S-016

Page 3

CERUMENEX® EARDROPS

(triethanolamine polypeptide oleate-condensate)

This product contains dry natural rubber

064550-OC-001

IT00412

DESCRIPTION

CERUMENEX Eardrops contain triethanolamine Polypeptide Oleate-Condensate (10%). Inactive Ingredients: Chlorobutanol 0.5%, Propylene Glycol and Water. Triethanolamine Polypeptide Oleate is a hygroscopic-miscible solution with low surface tension and optimal viscosity of 50-90 cps. It also has a slightly acid pH range (5.0-6.0) to approximate the surface of a normal ear canal.

CLINICAL PHARMACOLOGY

CERUMENEX Eardrops emulsify and disperse excess or impacted earwax. The triethanolamine polypeptide oleate, a surfactant, in a hygroscopic vehicle lyses cerumen to facilitate removal by subsequent water irrigation.

INDICATIONS AND USAGE

For removal of impacted cerumen prior to ear examination, otologic therapy and/or audiometry.

CONTRAINDICATIONS

Perforated tympanic membrane or otitis media is considered a contraindication to the use of this medication in the external ear canal.

A history of hypersensitivity to CERUMENEX Eardrops or to any of its components is also a contraindication to the use of this medication.

WARNINGS

Discontinue promptly if sensitization or irritation occurs.

PRECAUTIONS

General

It is recommended that the following precautions be observed in prescribing and administration of this agent:

1. Extreme caution is indicated in patients with demonstrable dermatologic idiosyncrasies or with history of allergic reactions in general.
2. Exposure of the ear canal to the CERUMENEX Eardrops should be limited to 15-30 minutes.
3. When administering CERUMENEX Eardrops, care must be taken to avoid undue exposure of the skin outside the ear during the instillation and the flushing out of the medication. If the medication comes in contact with the skin, the area should be washed with soap and water. Use of proper technique (see **DOSAGE AND ADMINISTRATION**) will help avoid such undue exposure.
4. CERUMENEX Eardrops should be used only with caution in external otitis.

Information for Patients

1. Patients should be cautioned to avoid placing the applicator tip into the ear canal.
2. Patients should be cautioned to gently flush the ear with lukewarm water.
3. Patients should be warned to use CERUMENEX Eardrops in ears only. Surrounding skin should be promptly rinsed of any excess drops.
4. Patients should be instructed not to leave CERUMENEX Eardrops in the ear for longer than 30 minutes. A second application may be made, if needed, but more frequent use must be indicated by the physician.
5. Patients must be instructed not to exceed the time of exposure, nor to use the medication more frequently than directed by the physician.
6. Patients should be advised to discontinue the use of the medication in case of a possible reaction and to consult their physician promptly.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies have not been performed to evaluate the carcinogenic potential or the effect on fertility of CERUMENEX Eardrops.

Pregnancy

Teratogenic Effects: Pregnancy Category C. Animal reproduction studies have not yet been conducted with CERUMENEX Eardrops. It is also not known whether CERUMENEX Eardrops can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. CERUMENEX Eardrops should be given to a pregnant woman only if clearly needed.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when CERUMENEX Eardrops are administered to a nursing mother.

Pediatric Use

Safety and effectiveness in children have not been established.

Geriatric Use

No overall clinical differences in safety or effectiveness have been observed between the elderly and other adult patients.

ADVERSE REACTIONS

Clinical Reactions of Possible Allergic Origin

Localized dermatitis reactions were reported in about 1% of 2,700 patients treated, ranging from a very mild erythema and pruritus of the external canal to a severe eczematoid reaction involving the external ear and periauricular tissue, generally with duration of 2-10 days.

Other reactions which have been reported in connection with the use of CERUMENEX Eardrops include allergic contact dermatitis, skin ulcerations, burning and pain at the application site and skin rash.

DOSAGE AND ADMINISTRATION

1. Fill ear canal with CERUMENEX Eardrops with the patient's head tilted at a 45° angle.
2. Insert cotton plug and allow to remain 15-30 minutes.

NDA 11-340/SLR-016

Page 6

3. Then gently flush with lukewarm water, using a soft rubber syringe (avoid excessive pressure). Exposure of skin outside the ear to the drug should be avoided. The procedure may be repeated if the first application fails to clear the impaction.

FOR EXTERNAL USE IN THE EAR ONLY

HOW SUPPLIED

CERUMENEX Eardrops (triethanolamine polypeptide oleate-condensate) are supplied in 6 mL (NDC 0034-5490-06) and 12 mL (NDC 0034-5490-12) bottles with a cellophane wrapped dropper.

Store at controlled room temperature 15-30°C (59-86°F). Store in a dry place.

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/s/

Wiley Chambers
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