
| RESEARCH ARTICLE

Earwax Removal Agents: Review article

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| ABSTRACT

Earwax (cerumen) is a natural secretion essential for ear health, but its impaction can lead to symptoms such as hearing loss, pain, and discomfort. This review article examines various earwax removal agents, classified into oil-based (e.g., olive oil, mineral oil, almond oil), water-based (e.g., sodium bicarbonate, saline, docusate sodium), and non-water/non-oil solutions (e.g., carbamide peroxide, glycerol, triethanolamine polypeptide). The review synthesizes findings from clinical studies, including a 2018 Cochrane Library review, which indicated that while active therapies improve complete earwax clearance (22%) compared to no treatment (5%), high-quality evidence supporting ear drops or sprays remains limited. Specific agents such as Cerumol®, Sofenz®, Otex®, and hydrogen peroxide are discussed in terms of their components, mechanisms of action (e.g., wax softening, gas bubble formation, hydration), efficacy, and adverse effects (e.g., irritation, pain). The article also highlights guideline recommendations from the British National Formulary (BNF) and the American Academy of Otolaryngology. It concludes that while many cerumenolytics are available, evidence varies, and patient-specific factors (e.g., eardrum perforation, age, infection) must guide treatment choices. Further well-designed randomized controlled trials are needed to address current evidence gaps.

| KEYWORDS

Earwax; Cerumen; Cerumenolytic; Ear drops; Earwax impaction; and Ear cleaning.

| ARTICLE INFORMATION

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Literature Review

Earwax (cerumen) impaction is a common clinical condition that can lead to hearing loss, pain, tinnitus, and discomfort. The self-cleaning mechanism of the ear canal can fail due to overproduction or improper cleaning practices, necessitating intervention. Various cerumenolytics have been developed, broadly classified into oil-based (e.g., olive oil, mineral oil, almond oil), water-based (e.g., sodium bicarbonate, saline, docusate sodium), and non-water/non-oil solutions (e.g., carbamide peroxide, glycerol, triethanolamine polypeptide).

A 2018 Cochrane Library review (Aaron et al.) including 14 randomized controlled trials (1,185 participants) found that active cerumenolytics achieved complete earwax clearance in 22% of cases compared to 5% with no treatment. However, the quality of evidence supporting ear drops or sprays was rated low to moderate, with many studies failing to report primary outcomes fully. The British National Formulary (BNF) recommends several agents, including olive oil, sodium bicarbonate, Cerumol®, and Otex®, while the American Academy of Otolaryngology emphasizes the use of docusate sodium followed by irrigation when needed.

Specific agents exhibit varied mechanisms: urea or glycerol enhances water penetration; peroxide-based agents release gas bubbles to mechanically dislodge wax; surfactants like docusate sodium and triethanolamine polypeptide reduce surface tension. Clinical studies have shown Sofenz (methyltrypsin and triethanolamine polypeptide) to achieve complete auditory canal visibility in up to 89.9% of patients after two administrations. Cerumol® (peanut oil and chlorobutanol) demonstrated superiority over dioctyl in some trials, though limitations include lack of long-term data on recurrence and infections. Natural agents like vinegar and olive oil are widely used but lack robust evidence; vinegar carries risks if the tympanic membrane is perforated. Overall, the literature indicates that while cerumenolytics are better than no treatment, high-quality evidence comparing different classes is insufficient, and patient-specific factors (e.g., eardrum integrity, age, infection) must guide therapy.

Methodology

This review synthesized information from peer-reviewed clinical studies, systematic reviews, randomized controlled trials (RCTs), and clinical guidelines. The primary sources included:

- The 2018 Cochrane Database Systematic Review (Aaron et al.) on ear drops for earwax removal.
- A 2010 Health Technology Assessment systematic review and economic evaluation (Clegg et al.).
- The 2017 updated Clinical Practice Guideline from the American Academy of Otolaryngology–Head and Neck Surgery.
- The British National Formulary (BNF) recommendations.
- Individual clinical trials and open-label studies on specific agents such as Sofenz (Midani et al., 2006), Cerumol®, Otex®, and others.
- Additional pharmacological and chemical data from DrugBank, PubMed, FDA labels, and specialized chemical databases (e.g., PubChem, ECHA).

Articles and references were accessed between April 2024 and June 2026. Inclusion criteria: studies evaluating cerumenolytic efficacy, safety, adverse effects, and patient-reported outcomes. Exclusion criteria: non-English publications, animal studies without human relevance, and case reports without controlled data.

Data extraction focused on:

- Complete earwax clearance rates
- Adverse effects (pain, irritation, discomfort)
- Need for further intervention (e.g., syringing)
- Symptom relief (hearing loss, tinnitus)
- Visibility of tympanic membrane post-treatment

No meta-analysis was performed; findings are presented narratively.

Introduction

Earwax, also called cerumen, is a normal body secretion that is an important part of the ear's self-cleaning system. But, when it blocks the ear canal it can produce symptoms such as hearing loss, pain and discomfort (1). Ear drops or sprays are often used in adults and children to eliminate or aid in the removal of earwax.

These liquids can be oil-based or water-based or non-water and non-oil based solutions. Dissolution by oil-based substances such as olive or almond oil softens the wax.

Water-based chemicals such as sodium bicarbonate improve water miscibility or water itself. They also utilize a mix of the above. Other non-water, non-oil solutions include carbamide peroxide, a hydrogen peroxide-urea combination, and glycerol (1).

In 2018 the Cochrane Library reviewed the effect of ear drops or sprays to remove or help remove earwax in adults and children. The study includes randomized controlled trials (RCTs) comparing a 'cerumenolytic' with no treatment, water or saline, an alternate liquid treatment (oil or almond oil) or another 'cerumenolytic' in adults or children with obstructed or impacted earwax. The main outcomes were percentage of patients (or ears) with full earwax clearance and adverse effects (discomfort, irritation or pain). Secondary outcomes were the amount of wax clearance, the proportion of people (or ears) with relief of symptoms due to wax, the proportion of people (or ears) requiring further intervention to remove wax, the success of mechanical removal of residual wax following treatment, and any other adverse effects recorded in the study. The review indicated a larger number of ears with complete earwax clearing in the active therapy group (22%) than in the no-treatment group (5%). But the research also found that there was little high-quality data to support using ear drops or sprays to remove earwax. The evaluation includes 14 trials of 1,185 people . Only 6 research reported the primary outcome of full earwax removal. The research indicated that ear drops or sprays were associated with a higher risk of unpleasant effects, such as discomfort, irritation or pain compared with no therapy or water or saline placebo.

The British National Formulary (BNF) recommends a number of treatments for ear wax removal including almond oil, olive oil, sodium bicarbonate drops, Cerumol®, Exterol®, Molcer®, Otex® and Waxsol® (2). These preparations are classified as water-based, oil-based, or non-water-non-oil-based goods.

The particular activity of these preparations is different. Thus in vitro experiments demonstrate that preparations containing urea or glycerine promote the penetration of water into earwax whereas preparations containing peroxide break up earwax by liberating gas bubbles and thereby facilitate mechanical removal.

Each of these methods has its pros and cons, and not all methods are good for all patients. In instance, the mechanical approaches mentioned here are less frequently performed in children (1). These medicines or drops are intended to soften the wax before removal at the clinic or to help it be removed on its own. How exactly they do it varies. For example, in vitro studies suggest that preparations containing urea or glycerine promote the penetration of water into earwax, whereas preparations containing peroxide break up earwax by generating gas bubbles, thus assisting mechanical removal.

1. Sodium Docusate

Components: Synthetic chemical substance which can be simply characterized as dioctyl sulfosuccinate as the sodium salt(3).

Properties: It is a drug often used as a stool softener to treat constipation, also known as docusate. It is an anionic surfactant that lowers stool surface tension to allow more intestinal fluids and fat to mix with it. This reduces the strain and discomfort of constipation (4).

Uses: Docusate sodium is also used as a cerumenolytic agent to soften and eliminate ear wax. It is occasionally used alongside ear syringing to help with the removal of earwax, especially in cases of impaction. Docusate sodium is a water-based substance that helps to hydrate and break down earwax, making cerumen removal easier and more effective (4).

Docusate sodium is recommended by the American Academy of Otolaryngology guidelines to see tympanic membranes that are occluded by cerumen. The use of docusate sodium, if necessary, is followed by irrigation (5).

Docusate sodium is not approved as a cerumenolytic, however it is used for this indication. The exact mechanism of action as a cerumenolytic is not clearly understood but it is considered to function by lowering the surface tension of the earwax, allowing water and lipids to penetrate and soften the earwax (5).

2. Cerumol®

Components: The active components are: Arachis oil refined (Peanut oil) 57% w/v, chlorobutanol and hemihydrate 5% w/v (6).

Properties: Prevent the illness. Chlorobutanol has antimicrobial characteristics that help prevent ear infections (7). Its capacity to soften and dissolve stubborn earwax making it easier to remove (8).

Uses: ear wax accumulation to soften and eliminate buildup; apply 5 drops in infected ear, fill with cotton wool, leave for 20 min (8). Cerumol has been tested in numerous clinical trials for its efficiency in ear wax elimination. For example, Cerumol was reported to be superior than dioctyl in eliminating earwax in a randomized controlled trial (9) and beneficial in dissolving earwax and allowing ear syringing in another investigation (10). However, it should be noted that these trials do not completely consider aspects such as recurrence, infections and frequent trips to GPs to adequately remove affected cerumen, which could alter the overall conclusion of the effectiveness of Cerumol (10).

3. Carbamide peroxide .

Components: (CH₄N₂O . H₂O₂) It is a chemical containing Hydrogen peroxide and urea, an organic compound(11) .

Properties: Pure carbamide peroxide is a crystal or crystal powder soluble in water(12) .

Uses: It is a cerumenolytic, which means it can soften, break down and remove earwax. Carbamide peroxide releases oxygen into the wax creating bubbles and softening it so that it is simpler to remove(13). It is frequently used with other products such as anhydrous glycerin to assist soften impacted cerumen and debride oral ulcers with its foaming action(14). You normally lie on your side, put the advised amount of drops into the ear canal and remain still for around 5 minutes and then dab the ear with a tissue. A 3% hydrogen peroxide solution is indicated which is also the concentration normally recommended for earwax removal. Carbamide peroxide is typically safe to use, although it can cause complications if a person has an ear infection or has damaged their ear. Before using any new ear drop solution, consult to a doctor and always follow the advice on the container. If a person has discomfort, a blocked ear or earache, or if the drops do not work, they should seek medical advice and treatment (13).

4. Vinegar Natural

Components: The components of natural vinegar include acetic acid, gallic acid, catechin, epicatechin, chlorogenic acid, caffeic acid, p-coumaric acid, and ferulic acid, which have therapeutic effects such as antioxidant, antidiabetic, antimicrobial, antitumor, antiobesity, antihypertensive, and cholesterol-lowering activities (15).

Properties: Physical and chemical properties Health benefits Its molecular weight is 60,052 g/mol. Density: 1.05 g/mol. It melts at 16,6 degrees (16).

Uses: Vinegar can be used as a cerumenolytic agent to soften and dissolve earwax for earwax removal. Water and water-based agents such as acetic acid and aqueous acetic acid cause cerumenolysis by hydrating and breaking down corneocytes (17). To use vinegar for earwax removal, dilute it with equal parts water or rubbing alcohol (isopropyl alcohol) so that it does not burn the delicate tissue of the ear canal (18). Using a clean dropper bottle or baby syringe, pour 5 to 10 drops of the liquid into each afflicted ear. Hold a cotton ball or a clean towel over the ear, and lie on your side for about 5 minutes to let the drops reach the ear. This application can be repeated as often as desired to treat an outer ear infection (18). But it is crucial to highlight that vinegar is to be used only for outer ear infections and not for middle ear infections which require medical attention especially in children. If the tympanic membrane (eardrum) is not intact, do not put anything in the ear without seeing a doctor. If an earache or infection persists for 3 days or if there is discharge, fever or loss of balance, a doctor should be called (18).

5. Mineral oil

Components: Mineral oil is composed of saturated paraffins (alkanes), naphthenes, and aromatics¹.The specific composition of chemicals in mineral oil depends on the petroleum source and the refining conditions (17)

Properties: Mineral oil is a liquid by-product or hydrocarbon fluid obtained from the distillation of crude oil (20). It is a clear, colorless oil comprised mostly of alkanes and cycloalkanes, and is related to petroleum jelly. The density of mineral oil is 0.8-0.87

g/cm³ (0.029-0.031 lb/cu in). Mineral oil has low heat conductivity and electrical conductivity. Therefore, it is the most suitable for electrical and industrial industries (21). Its dielectric constant varies from 2.3 at 50°C (122°F) to 2.1 at 200°C (392°F).

Uses: Mineral oil is frequently utilized for earwax removal since it softens and lubricates the earwax, making it easier to remove. It is safe to use in those who have ear tubes or a hole in the eardrum (22). Mineral oil is available over the counter at most drug stores without a prescription and it usually comes in a large bottle. A little dropper bottle is ideal for placing the mineral oil in the ear. At bedtime, place the oil in the affected ear to soften hard or dry wax overnight. You can use the washcloth in the morning to wipe away any excess oil and earwax from the outer ear. Mineral oil can be used daily during periods of significant wax buildup and once or twice weekly for maintenance (22). A systematic analysis of randomised controlled studies indicated that ear drops, including mineral oil, may raise the proportion of ears cleared of wax from 1 in 20 (if no therapy is given) to around 1 in 5 (23). But there is little evidence that water based or oil based drops are any different from saline or water, or that saline or water are any better than doing nothing. Side effects of ear drops are often modest and include slight discomfort or an unpleasant smell (23).

6. Sofenz

Components: The major components of Sofenz ceruminolytic solution are methyltrypsin and triethanolamine polypeptide (24). Methyltrypsin is an enzyme that breaks down proteins in earwax to make it simpler to remove. Triethanolamine polypeptide is a surfactant that helps to dissolve and soften the earwax, allowing it to be removed (24).

Properties: Methyltrypsin-containing earwax removal solution, safe and efficacious in an open-label investigation of 109 untreated individuals (24).

Uses: Sofenz is a ceruminolytic solution used for the treatment of excessive or impacted cerumen in the external auditory canal. It is applied for 15 minutes and then followed by irrigation with warm water. The treatment is safe, well-tolerated, and effective with a high level of patient satisfaction (24). The main efficacy measure is the visibility of the tympanic membrane after the solution has been emptied from the canal and after repeated irrigation. The study showed that 1 or 2 administrations of Sofenz with irrigation with lukewarm water led to complete visibility of the external auditory canal in 74.3% and 89.9% of the patients, respectively. Secondary outcome measures Improvement in otologic symptoms (hearing loss, tinnitus) Satisfaction with treatment. The study showed a 93.2% reduction in otologic symptoms at the safety follow-up visit and a high level of satisfaction with therapy stated by each patient in a self-assessment. Reported adverse effects were brief and mild or moderate, with just 16 incidents obviously connected to treatment. Irrigation with lukewarm water after treatment with Sofenz is advantageous not only for enhancing tympanic membrane visibility but also for clinically relevant endpoints, such as reduction of otologic symptoms (24).

7. Peroxide, hydrogen

components: The major ingredients of hydrogen peroxide are oxygen (O₂) and hydrogen (H). It is a simple chemical comprising of two atoms of hydrogen and two atoms of oxygen. Its molecular formula is H₂O₂ (25).

Properties: General features Hydrogen peroxide (H₂O₂) has many general features. It is a very faint blue liquid, a little more viscous than water (26). In its pure form hydrogen peroxide is more viscous and denser than water, with a density of 1.44g/cm³ (27). The molecule is asymmetric and highly polarized, therefore it is prone to forming hydrogen-bond networks, which could explain its increased viscosity compared to water (26). Hydrogen peroxide is a widely used oxidizing agent, bleaching agent, and antiseptic. It is usually used in dilute solutions (3%–6% by weight) for consumer uses and in more concentrated forms for industrial applications (27). Also, concentrated hydrogen peroxide ("high-test peroxide") decomposes explosively upon heating, and has been utilized in rocketry as a monopropellant and as an oxidizer (27).

Uses: Hydrogen peroxide can be used to loosen excess wax before removal from the ear canal. It works by breaking down earwax with gas bubbles, softening it and helping to eliminate it. Hydrogen peroxide for ear wax removal must be diluted with water. Usually, the dilution ratio is 1:1. The technique is to pour a diluted hydrogen peroxide solution into the ear canal, wait a minute for it to bubble and fizz, then tilt the head to allow the solution and wax to drain into a tissue. This can be performed on a daily basis for 3-5 days until no more wax is visible. However, do not use hydrogen peroxide if you have a hole in the eardrum, or if you suspect a perforation, or if you have grommets, or if you have any irritation or pain in the ear. In such instances, it is advisable to get guidance from a medical practitioner to guarantee safe and proper ear care (28).

8. Hydroxyquinoline,

Components: 8-Hydroxyquinoline consists of two major components, a heterocycle quinoline and a hydroxy group at position 8. 8-Hydroxyquinoline, also called oxine, is an organic molecule formed from quinoline, a white solid used as a chelating agent for metal ions. It forms chelate complexes with metal ions, losing a proton and interacting with them (29).

Properties: 8-Hydroxyquinoline general qualities include application as a fungicide, primarily in horticulture, high water solubility, moderate volatility, and a low danger of leaching to groundwater (30). Not persistent in soil systems but may be persistent in aquatic systems under specific conditions. The chemical is somewhat toxic when taken orally in rats and can adversely affect human health as it is a possible mutagen that can cause harm to reproduction and development. It is also hazardous to birds

and mildly toxic to most aquatic life, honeybees and earthworms (31). 8-Hydroxyquinoline is a quinoline fungicide that can be used preventively and curatively to manage a range of diseases on vines and other crops such as grey mold, downy mildew, Fusarium and Verticillium. It has been used extensively and its efficacy tested in field studies and it has regulatory approval in some countries (30).

Uses: 8-hydroxyquinoline is a constituent in several ear drops, such as Otex, which are used to assist eliminate hardened wax from the ear canal (32). This chemical is particularly effective at breaking down stubborn, compacted ear wax. Otex ear drops contain 8-hydroxyquinoline and have been proved clinically to help clear hardened ear wax, and are the UK's best selling ear wax removal drops. The composition is based on Exterol ear drops, which was intended for healthcare professionals to administer as an assist in earwax removal (33). The Otex formulation is clinically established and has been evaluated in several trials which have found it to be effective in reducing the need for ear syringing and well tolerated by patients. For use, press up to 5 drops into the afflicted ear with your head tilted. Allow the drops to stay for a few minutes and then dab away any excess with a tissue. Repeat once or twice daily for about 3 to 4 days until symptoms disappear (34). To avoid any mishaps, the drops should be kept upright and away from the reach of children for safe and effective wax removal. Discontinue medication and consult your doctor if you suffer any irritation or pain during use (34).

9. Glycerol (glycerin)

Components: Glycerol, often known as glycerine or glycerin, is a simple triol molecule. It is a prochiral molecule with three hydroxyl groups (35).

Properties: it is colorless, odorless, viscous, sweet-tasting, and non-toxic (35). It is miscible with water and is hygroscopic. Glycerol is frequently utilized as sweetener in food sector and humectant in pharmaceutical formulations. It is also employed in the manufacture of numerous explosives, including nitroglycerin, which is used for the relief of angina pectoris (35).

Uses: Glycerol is used to soften ear wax to facilitate its evacuation from the ear canal. It has a modest keratolytic activity, which reduces the keratin load in the debris, so that other components are able to reach the skin underneath and exert their action (36). Ear drops often contain glycerol coupled with additional chemicals, such as urea or hydrogen peroxide, to soften earwax and help remove it (36).

10. Oil of chlorbutol

Components: Chlorbutol is a volatile bacteriostatic and anti-fungal agent active against Gram-positive and Gram-negative bacteria including *Pseudomonas aeruginosa* (37). In topical preparations for treatment of earwax, chlorbutol is frequently formulated with oils such as arachis oil, almond oil and olive oil, as well as other ingredients such as para-dichlorobenzene, oil of turpentine and 3-methoxybutyl acetate (38).

Properties: Chlorobutanol (also called Chlortran, Chloreton, YM-57158, Chlorbutol, and Chloreton) is a chemical preservative and a sedative-hypnotic and a weak local anesthetic (39). It possesses antibacterial and antifungal activity, and is generally employed at a concentration of 0.5% to provide long-term stability to multi-ingredient formulations (39). Chlorobutanol is soluble in water, alcohol, chloroform, ether, glycerol, glacial acetic acid, oils, petroleum ether, and acetone (40). It has a melting point of 97°C for the anhydrous form and 78°C for the hemihydrate form and a boiling temperature of 167°C for the anhydrous form and 135°C for the hemihydrate form (41). It is used in many medicinal and cosmetic preparations, including injections, ointments, treatments for the eyes, ears and nose, and dental preparations at a concentration of 0.5%. It has been in use for almost 130 years and is produced in a modern plant that is accredited to EN ISO 9001 and EN ISO 14001 standards. The plant is certified to operate under stringent c-GMP conditions and has passed rigorous on-site inspections (42).

Uses: Oil chlorbutol is used as an ingredient in ear drops to help eliminate earwax. It is part of a class of drugs called Otic agents and is helpful in softening and helping to remove earwax build-up. Oil chlorbutol, coupled with constituents such as turpentine oil, benzocaine and paradichlorobenzene, helps to soften earwax without pain or suffering. These ear drops are mostly used to treat earwax buildup due to illnesses including ear infections, inflammation, injuries, or other ear-related issues. Oil chlorbutol is a wax softener and together with other substances, it helps to the overall effectiveness of the ear drops in the management of ear wax build up (43).

11. Oil Triethanolamine

Components: The major components of oil triethanolamine are triethanolamine (C₆H₁₅NO₃) and water (H₂O). Triethanolamine is a colorless to pale yellow viscous liquid used in the synthesis of emulsifiers and other chemical products (44). It is a tertiary amine made by the reaction of ammonia with ethylene oxide.

Properties: Triethanolamine (TEA) is a bifunctional molecule that exhibits both alcohol and amine characteristics (45). It is commercially available with a purity of 99.0% min and may contain tiny quantities of diethanolamine and ethanolamine. The relative vapour density of the compound is 5.14, the flash-point is 185 °C and the octanol/water partition coefficient (P) is -2.3. It is not compatible with metals like aluminum and copper, halogenated organics, strong acids, oxidizing compounds, and absorbent materials (cellulose, sawdust) (46). Triethanolamine is utilized in several applications, including as a corrosion inhibitor

in metal-cutting fluids, as a curing agent for epoxy and rubber polymers, and as an additive in copper–nickel plating baths (46). It is also employed in the manufacture of cosmetics and pharmaceuticals where it may serve as an antioxidant against auto-oxidation of animal and vegetable lipids (47). Triethanolamine is a liquid with a melting point of 21.6 °C and a boiling point of 335.4 °C in terms of its physical qualities. The compound is miscible in water and water solubility is 497.0 mg/mL. The compound has a logP of -1.59 and a pKa of 7.76 (47).

Uses: Triethanolamine polypeptide is used as a constituent in some ear drops to help eliminate earwax. In a randomized clinical trial a non-water-non-oil-based preparation was proven more effective than an oil-based preparation both in removing earwax without syringing and in assisting successful syringing (48). However, there is little evidence that triethanolamine polypeptide is better than alternative therapies such as saline or water (49). The time before syringing that preparations are used seems less important than for earwax clearance (48). Wax hardens with age and preparations are more effective in children than adults (50). A preparation in water or oil applied 15 to 30 minutes before syringing is probably as effective as a lengthier application. Non-water- or non-oil-based therapies show promise for removing earwax, but require several days of treatment. Further well-designed randomised studies of the three classes of medicines are required to cover the current gaps in evidence (48).

12. Propylene glycol .

Components: The primary components of PG are propylene oxide and water. The PG is manufactured from propylene oxide by non-catalytic oxidation. The result is purified by distillation to a nearly pure (99%) product. The ingredient is available as "technical grade" or USP grade, the latter of which is most usually used in the preparation of pet food. PG is a difunctional alcohol, including a primary and a secondary hydroxyl group, which distinguishes it from ethylene glycol, which contains two primary hydroxyl groups (51).

Properties: Propylene glycol is a colorless, odorless, and non-toxic organic molecule with a chemical formula of C₃H₈O₂ (52). It is a diol, meaning it has two alcohol groups, and is miscible with a wide range of solvents, including water, acetone and chloroform. It has a low freezing point, is a good antifreeze and heat transfer agent, and is chemically stable with strong solvency qualities (53).

Uses: Propylene glycol is utilized as a viscous carrier in topical ear treatments so that maximum contact time with the cerumen in the ear canal can be achieved. It is often used in combination with other agents such as carbamide peroxide which releases oxygen to damage the integrity of impacted wax, permitting its simple removal (54). It is also utilized in several cerumen removing solutions and preparations as it softens impacted cerumen for removal. For ear wax removal, propylene glycol is employed as a vehicle for topical ear treatments, providing maximum contact time with the cerumen in the ear canal and allowing the removal of excessive cerumen or treatment of ear infections, inflammation or pain (54).

13. DermOtic Oil

Components: The active ingredients of DermOtic® Oil are fluocinolone acetonide, isopropyl alcohol, isopropyl myristate, light mineral oil, oleth-2, refined peanut oil NF, and scents (55). DermOtic® Oil is produced with 48% refined peanut oil NF, which is consistently tested for peanut proteins by amino acid analysis, with amino acid levels below 0.5 parts per million (ppm) (56).

Properties: Do not use if allergic to any of the components of this product, especially refined peanut oil. Do not apply to the eye or eye area and do not use if you have a ruptured eardrum, ear tubes or an untreated ear infection. The product is for otic use only and should not be used on the face, underarm or groin. If it gets into the eyes, rinse well with water. Recommended dose. For Chronic Eczematous External Otitis in Adults and Children 12 Years and Older, instill 5 drops into the afflicted ear using the ear dropper provided (57).

Uses: DermOtic oil (sweet oil) is used to eliminate earwax. It can soften and break up ear wax and make it easier to remove. A 2010 study revealed sweet oil to be better than no treatment for removing earwax but not as effective as prescribed ear drops. Other research reveal that sweet oil is just as effective as commercial ear drops in eliminating earwax. Traditionally sweet oil is used for many ear problems, such as earwax removal, earache and ear infections (57). Sweet oil is indicated for the elimination of earwax twice a day.

14. Bicarbonate of soda

Components: sodium bicarbonate is composed of Sodium (Na), Hydrogen (H), Carbon (C) and Oxygen (O). It has a chemical formula of NaHCO₃, which implies that its molecular structure contains one atom of sodium (Na), one atom of hydrogen (H), one atom of carbon (C), and three atoms of oxygen (O) (58).

Properties: Sodium bicarbonate, popularly known as baking soda, is a white crystalline powder that has a slightly alkaline flavor. It is odorless, water-soluble, stable in dry air, but decomposes slowly in moist air. Sodium bicarbonate interacts exothermically with acids to give non-toxic carbon dioxide gas and decomposes on heating over 50 °C. It is widely employed in many sectors as a buffering agent, blowing agent, catalyst and chemical feedstock. In medicines it is used as an antacid, buffering agent and as a source of carbon dioxide in effervescent tablets[1]. Sodium bicarbonate is also found in fire extinguishers, water treatment, oil

well drilling and the manufacturing of sodium salts. It reacts with acids and acid salts and also with alkaloid salts with evolution of carbon. The chemical is stable in a well closed dry location. It may be refined by crystallization from hot water (59).

Uses: Sodium bicarbonate ear drops are a gentle and effective technique to soften ear wax to help unclog the ears and make it easier to remove (60). These drops dissolve earwax chemically rather than softening it, allowing for faster removal than conventional techniques such as olive oil (61). They are alkaline, to neutralize the acidic nature of ear wax, and speed the softening, therefore decreasing the need for mechanical removal (62).

15. Salicylate of choline

Components: The primary components of Choline salicylate are Choline and Salicylate. Choline is a quaternary ammonium cation and a structural component of phospholipids and a methyl donor in metabolic one-carbon chemistry. Salicylate is derived from the popular anti-inflammatory drug salicylic acid (63).

Properties: Choline salicylate is a non-acetyl salicylate medication, related to aspirin. It is used as a moderate analgesic, having a similar effect as lignocaine hydrochloride for the treatment of pain (64). It is a non-irritating chemical that is available in a variety of medication forms such as solid (e.g., tablets and lozenges) and liquid (e.g., ear drops) (63). It is a derivative of salicylic acid and inhibits prostaglandin synthesis, giving anti-inflammatory, analgesic and antipyretic properties. It is used to relieve edema and to treat mild to severe discomfort (65).

Uses: Choline salicylate is used in ear drops to soften stubborn earwax to make it simpler to remove. This is done by softening the built up ear wax and removing it from the ear. Choline salicylate has anti-inflammatory and analgesic effects that may help reduce symptoms of otitis media, infections and inflammation of the eardrum and external auditory canal (66). A study indicated that using any sort of ear drops, including those with choline salicylate, is better than no treatment for eliminating earwax (67). Choline salicylate is available in the form of ear drops and sprays which can be placed directly into the ear canal. This medicinal product contains twice the amount of active ingredient compared to other medicinal products with 200 mg/g of choline salicylate (66).

16. Oils of Olive

Components: The major components of olive oil include triglycerides, fatty acids and minor chemicals, such as phenolic compounds, sterols, tocopherols, minerals and other beneficial substances. Fatty acids composition of olive oil mostly consists of monounsaturated fatty acids (MUFAs), especially oleic acid, which represents for 80% of the total fatty acid content. The olive oil contains 3–22% polyunsaturated fatty acids (PUFAs), whereas saturated fatty acids (SFAs) and linoleic acid are 8 to 26% of it (68).

Properties: Olive oil is one of the fats derived from the fruit of the olive tree, *Olea europaea*. It is characterized by distinct chemical and physical qualities influenced by factors such as the cultivar, habitat and cultural techniques (69). Olive oil is obtained solely by mechanical or physical means and without the use of heat treatment or refining and without any treatment other than washing, decantation, centrifugation and filtering. It is green to yellow in color and has a characteristic taste (69). The stability of the antioxidant capacity of virgin olive oil is attributed to the high level of monounsaturated fatty acids, low content of polyunsaturated fatty acids and the presence of natural antioxidants such as phenols, tocopherols and carotenoids. The European Union (EU) classifies numerous varieties of olive oil, such as virgin olive oil (VOO), extra-virgin olive oil (EVOO), refined olive oil, olive oil, olive pomace oil and lampante olive oil (69).

Uses: Olive oil can soften earwax, making it easier to remove. It is a mild approach that lubricates the skin inside the ear and helps to soften the earwax plug (70).

Use conservative amounts of olive oil and don't let it sit on for long to avoid accumulation (71).

17. Squalene

Components: Squalane is an oily liquid with a long shelf life, as it is a saturated hydrocarbon made up of solely carbon and hydrogen. It is naturally found in several fish and plant oils, such as olive oil and human skin sebum (72).

Properties: Squalane is a saturated hydrocarbon, generated from squalene, a triterpene present in different animals, including humans, sharks and plants (73). It is a stable, colourless, odourless, tasteless, transparent oil to air and oxygen (74). Squalane is very soluble in many organic solvents such as ether, gasoline, petroleum ether, benzene, chloroform, and oils but slightly soluble in methanol, ethanol, acetone, and glacial acetic acid (74). Squalene is a hydrocarbon that is unsaturated, has a faint agreeable odor, and is practically insoluble in water but is freely soluble in ether, petroleum ether, carbon tetrachloride, acetone, and other lipophilic solvents (74).

Uses: Is a chemical which has been utilized as an emollient in ear cleaning products (75). It is present in products such as Miracell® for human use and Cerumene® for veterinary usage. Squalane has been utilized in ear cleaning solutions for the removal of earwax and to promote the penetration of active substances. It is also called in the U.S. Ingredient of preparations for the treatment of otitis in dogs and cats. Patent No. 3,821,375. Squalane is a base ingredient in human and veterinary ear cleaning products and has demonstrated effectiveness in eliminating earwax and enhancing the penetration of therapeutic substances.

Note that health professionals do not promote ear wax self-treatment with cotton swabs or other techniques since it might

cause skin irritation and infection (75). Impacted cerumen may require professional intervention for safe and effective alleviation and removal (76).

18. Salt Water

Components: Saline is a combination of water and salt (sodium chloride). It is used in medicine for a number of applications including cleaning wounds, removing and storing contact lenses and as fluid replacement during medical procedures. Normal saline (0.9 % saline) is the most often used saline in medicine. It contains 0.9 grams of sodium chloride per 100 milliliters of solution or 9 grams per liter. This is equivalent to an osmolarity of around 308 mOsm/L and an ionic concentration of sodium 154 mEq/L and chloride 154 mEq/L (77).

Properties: Saline is a combination of sodium chloride (salt) and water. It has several applications in medicine, including wound cleansing, removal and storage of contact lenses and intravenous therapy (78).

Uses: It is often used for ear wax removal as it is efficient in softening and dissolving ear wax. It can be used as a gentle, water-based ear wax removal spray that is well tolerated by most people. Saline solutions work faster than other techniques, such as olive oil, since they chemically dissolve earwax, rather than simply softening it. Saline ear drops are inexpensive and fast and can be used for a day or two without any problems. But overuse of saline solutions can remove the protective lining of the ear canal and lead to infection. Saline is widely advised for earwax removal as it is safe and comfortable for many people (79).

Results/Findings

1. Efficacy of Cerumenolytics

- o Active therapy groups had 22% complete earwax clearance vs. 5% in no-treatment groups (Cochrane 2018).
- o Sofenz®: After 1 administration, 74.3% achieved full tympanic membrane visibility; after 2 administrations, 89.9% (Midani et al., 2006).
- o Cerumol®: Superior to dioctyl in one RCT; beneficial for facilitating syringing.
- o Triethanolamine polypeptide (non-water/oil): More effective than oil-based preparations for wax removal without syringing.
- o No significant difference found between water-based, oil-based, and saline/water in most head-to-head comparisons.

2. Adverse Effects

- o Ear drops/sprays associated with higher risk of discomfort, irritation, or pain compared to no treatment or saline placebo.
- o Sofenz®: 16 mild-to-moderate treatment-related adverse events reported; generally well-tolerated.
- o Hydrogen peroxide and carbamide peroxide: Can cause local irritation, especially if eardrum perforated.
- o Vinegar: Risk of burning sensation; must be diluted; contraindicated with non-intact tympanic membrane.

3. Specific Agent Findings

- o Docusate sodium: Not FDA-approved as cerumenolytic but recommended by AAO-HNS; mechanism involves surface tension reduction.
- o Carbamide peroxide: Releases oxygen bubbles; requires 5-minute application; safe unless infection or perforation present.
- o Mineral oil: Safe with ear tubes or perforated eardrum; increases clearance from 5% (no treatment) to ~20%.
- o Sodium bicarbonate: Alkaline, chemically dissolves wax faster than oils.
- o Olive oil: Softens wax but slower; minimal adverse effects.
- o Glycerol: Mild keratolytic; often combined with urea or peroxide.
- o 8-Hydroxyquinoline (Otex®): Effective for hard, compacted wax; UK best-selling ear drop.
- o Choline salicylate: Provides anti-inflammatory/analgesic effects; may help with otitis media symptoms.

4. Guideline Recommendations

- o BNF: Almond oil, olive oil, sodium bicarbonate, Cerumol®, Exterol®, Molcer®, Otex®, Waxsol®.
- o AAO-HNS: Docusate sodium followed by irrigation if needed; avoid routine syringing.

5. Evidence Gaps

- o Low-quality evidence for most comparisons.
- o Few RCTs report primary outcome of complete clearance.
- o Lack of studies on recurrence, long-term safety, and pediatric populations.

Conclusion

This review confirms that cerumenolytics are more effective than no treatment for earwax impaction, achieving complete clearance in approximately one in five patients compared to one in twenty with no intervention. However, the overall quality of evidence supporting specific ear drops or sprays remains low to moderate, with considerable variation in study design, outcomes, and reporting.

Oil-based agents (e.g., olive oil, mineral oil) are safe, readily available, and suitable for maintenance therapy or use with perforated eardrums. Water-based agents (e.g., sodium bicarbonate, saline, docusate sodium) act more rapidly through hydration or surfactant effects. Non-water/non-oil solutions (e.g., carbamide peroxide, triethanolamine polypeptide) offer mechanical disruption via gas bubble formation or enhanced penetration but often require multiple days of treatment.

No single agent is universally superior; treatment choice must be individualized based on:

- Tympanic membrane integrity (avoid peroxide, vinegar if perforated)
- Presence of ear tubes or infection
- Patient age (children less responsive to some preparations)
- Prior adverse reactions (e.g., peanut oil in Cerumol®)

Adverse effects are generally mild but include pain, irritation, and unpleasant smell. Mechanical removal (syringing, microsuction) may still be required after cerumenolytic use.

Future directions: Well-designed, large-scale RCTs comparing the three classes of cerumenolytics against standardized saline or no treatment, with consistent primary outcomes (complete clearance, symptom relief, safety) and long-term follow-up for recurrence and complications.

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All data referenced in this review are available from published sources, including the Cochrane Library, PubMed, drug regulatory agencies, and publicly accessible chemical databases. No new primary data were generated.

Disclaimer:

The information provided in this review is for educational and clinical guidance purposes only. Healthcare providers should consult original sources, local formularies, and patient-specific factors before recommending or prescribing any earwax removal agent. The author and Mazaya University College assume no liability for adverse outcomes arising from the use of any product discussed herein.

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