

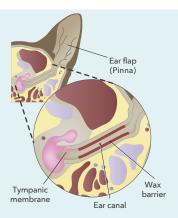
Up to 20% of dogs and 5% of cats suffer from some form of ear disease¹



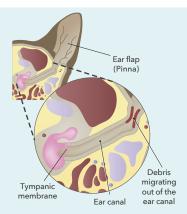
THE NORMAL EAR

Cerumen is a complex mixture of desquamated keratinocytes and debris in combination with secretions of both the ceruminous and the sebaceous glands of the external ear canal, which contribute waxes, oils, free fatty acids and immunoglobulins.2,3

In the external ear canal, cerumen influences the effectiveness of the underlying cutaneous epithelial barrier. The presence of cerumen is normal and is mandatory for the physiological movement of microorganisms or foreign substances from the deep ear canal towards its external opening.3



Cerumen functions as a protective and antimicrobial barrier which traps debris in the ear canal.



Debris entering the ear canal is trapped and removed with cerumen due to the lateral/ outward migration of the stratum corneum.

OTITIS EXTERNA

Otitis externa is an acute or chronic inflammatory disease of the external ear canal, including the ear pinna.4 Canine otitis externa (OE) is one of the most common diseases in small animal practice.³ The aetiology of OE is multifactorial and typically involves predisposing factors (which may make otitis more likely but do not cause disease on their own), primary factors (which trigger otitis), and secondary factors (which amplify the severity of otitis).5

Predisposing factors of otitis externa:

• Conformation • Canal stenosis • Genetics

Most common primary causes of otitis externa:

- Allergies
- Foreign bodies
- Ectoparasites
 Failure of self cleaning

Secondary factors of otitis externa:

- Bacteria
- Yeast

Note that overtreatment, irritant or topical drug reactions can both trigger and/or exacerbate otitis.

? Did you know?

Infection is always secondary

In cases of OE, bacterial and yeast infections can occur as a result of the inflammatory process created by the primary disease. Appropriate topical ear cleaners and prescription medicated drops must be used for ear disease to resolve.

The connection between atopy and otitis externa in dogs

The external ear canal in the dog is similar in structure to the interfollicular epidermis of the skin. It is stratified cornified epithelium with adnexal organs, such as hair follicles and their associated sebaceous and ceruminous glands. Therefore, any disease that affects the skin can also affect the external ear canals.8

Allergies, especially atopic dermatitis, are the most common primary trigger for otitis externa in dogs. Ear disease recurs, and acute disease progresses to chronic, often irreversible disease when there is a failure to identify and manage the primary cause (or causes) for the presenting otitis externa.8

In dogs with allergies as the primary trigger (e.g. atopy, food allergies and contact allergies), skin barrier function may be compromised and it's vital to ensure that any cleansing solutions used are well tolerated and do not exacerbate inflammation or irritation.



of dogs diagnosed with atopic dermatitis may show signs of otitis externa.7



of atopic dogs may show no clinical signs other than otitis externa.7

Ear cleaners: options and indications

Choosing the most appropriate ear cleaner is akin to selecting a shampoo. Whether an ear cleaner is required, and if so, which product is required, depends on the individual patient and may change as treatment progresses.²

A clean ear canal is imperative for successful otitis therapy. How aggressive cleaning needs to be is based on the amount of inflammation and degree of exudate, wax, or debris that is being produced, which depends on the primary condition and perpetuating factors.

For the treatment of otitis externa, multipurpose otic preparations exhibiting anti-bacterial, anti-fungal or anti-inflammatory properties are typically indicated and often prescribed concurrently to an ear cleaner, due to the mix of microorganisms in infectious otitis externa and inflammation at the time of diagnosis.⁴



FUNCTIONS OF EAR CLEANERS

ALKALINISING

Alkalinisers have been shown to enhance the antimicrobial effect of many aminoglycoside and fluoroquinolone antibiotics. A specific alkaliniser, tris-EDTA (trisamino-methamine-ethylenediaminetetra acetic acid) is a common ear product for treatment of gram-negative bacterial otic infections.¹¹

ACIDIC

Acids change the pH of the ear canal and inhibit growth and reproduction of many infectious organisms.⁹

DRYING

Astringent (drying agents) are typically alcohols e.g. isopropyl alcohol. Acids at low pH can be drying, and aluminium acetate (Burrow's solution) is particularly drying. In ear cleaners, astringents are used to minimise the risk of maceration. Some, typically alcohol containing ones, are used prophylactically after water is introduced into the ear canal e.g. after bathing or swimming. Most astringents should be used cautiously in inflamed ears as there is a risk of irritation, which can also occasionally be seen in non-inflamed ears.

ANTISEPTIC

Many ear cleaners have demonstrable antimicrobial effects and can be effective in mild cases of infectious otitis as sole therapies. They may also have adjunctive effects when used in combination with antibiotic / glucocorticoid topical therapies, typically shortly before their application ^{12, 13, 14} because the pH of the ear canal returns to baseline within a short time (hours) following therapy. ¹⁵

CERUMINOLYTIC

Ceruminolytic ear cleaners can contain a variety of ingredients including organic oils and other solvents (including alcohol), depending on the formulation used, that soften and loosen cerumen. They are used to effectively clean and remove ceruminous wax from ears as an important part of treatment and may be used as a maintenance therapy for otitis on an ongoing basis.⁹

A CLOSE-UP ON CERUMINOLYTIC EAR CLEANERS

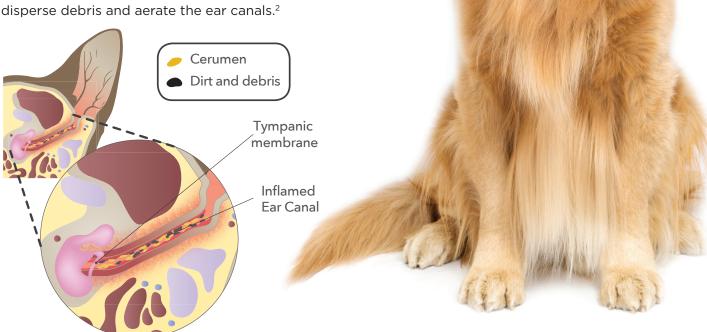
When self-cleaning fails

The presence of cerumen is normal and is mandatory for the physiological movement of microorganisms or foreign substances from the deep ear canal towards its external opening. This lateral (outward) migration is facilitated by the stratum corneum.²

When lateral migration is impaired, debris and cerumen accumulate in the ear, predisposing to otitis.

Ceruminolytics soften and dissolve cerumen and most commonly come in the form of organic oils and solvents. They are particularly useful in mildly waxy or dirty ears and are relatively safe for routine at-home cleaning if the tympanic membrane is intact.²

Surfactants in ceruminolytic ear cleaners help enhance the cleaning process by emulsifying debris, breaking it up and keeping it in solution. Foaming agents such as urea and carbamide peroxides release oxygen to help disperse debris and aerate the ear canals.²



PAW GENTLE EAR CLEANER



Features & Benefits:

- → Gentle ceruminolytic ear cleaner
- Utilises cold pressed citrus oil & gentle surfactants to effectively remove cerumen without compromising the skin barrier
- + Reduces ear odours
- Contains no alcohol or acids
- Easy to apply using the flexible applicator nozzle
- Once a week maintenance application
- Suitable for dogs & cats

Key ingredients:

- Cold-pressed citrus oil
- · Hydrolysed oat protein
- · Deionised water
- Gentle botanically derived surfactants

Dosage: Once-a-week for maintenance of a healthy ear environment

Size: 120ml bottle

Storage: Store below 30°C

Warnings/Safety:

- · For animal use only.
- Do not use if tympanic membrane is ruptured.
- Please read the label and follow the directions for use.

Using ceruminolytics in the treatment of otitis externa



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Chronic or relapsing otitis externa is a common reason for referral (of dogs especially) to our clinic. While some of these cases can be significantly more severe than cases seen in routine practice, we still see a surprising number of more 'routine' otitis externa cases, especially in our allergic dogs.

Successful therapy of any case of otitis requires three basic things – successful drug penetration, correct selection of antimicrobials and normalisation of the ear canal, particularly with respect to inflammation. The most common cause for treatment failure in our experience is the first of these, failure of topical drug penetration, and this is usually due to a build up of exudate in the ear canal coupled with inadequate cleaning.

In my hands, PAW Gentle Ear Cleaner plays a couple of roles to try and address this exudate build up and subsequent failure of drug penetration.

As part of ear cleaning under anaesthesia

Following gross removal of exudate using forceps and warm saline flushing, so long as the ear drum is confirmed intact, PAW Gentle Ear Cleaner is very useful for removal of remaining debris from the canal. However, it should not be used if the ear drum is not intact or if there is a risk of perforation. The surfactant cleaning action is effective for both purulent and waxy debris, though macerated keratinous debris, as with all cleaners, remains a challenge. Typically we will fill the ear with the PAW Gentle Ear Cleaner, massage well for 1-2 minutes then initially suction out the liquid and debris. This is followed by several cycles of flushing the ear with saline, then suction of the saline and debris. This process is continued until both the canal is free of debris, and the residual bubbles from the PAW Gentle Ear Cleaner are are no longer evident. Figures 1-4 show this process.

Ceruminolith removal

Ceruminoliths (plugs of ear wax and desquamated keratinocytes, typically lodged in the osseous canal in front of the tympanic membrane) are not uncommon as a consequence of failure of the self-cleaning mechanism in the ear. This can be seen following chronic otitis externa, and sometimes idiopathically, often in dogs with congenitally narrowed osseous canals. These can be sterile or entrap bacteria and/or yeast. Removal is typically straightforward using forceps and video otoscopy under anaesthesia, but this is not always an option for some clients and patients.

In some of these cases, I recommend PAW Gentle Ear Cleaner used twice weekly to fill the ear canal, then massage for 1-2 minutes. This is important since the plugs are typically lodged deep to the ear cartilage and so we are relying on the chemical action of the cleaner to gradually break the plug up. Following this the dog is allowed to shake out the cleaner and the excess is wiped out. This procedure is immediately repeated using a more aqueous cleaner preferably containing lactic acid that is less effective at wax removal to 'rinse' out the broken down waxy material. This is akin to rinsing the shampoo off after a bath, and in our experience, while the PAW Gentle Ear Cleaner is effective at breaking down the wax, following this with a rinse tends to be more effective as a complete cleaning regime.

Rechecks are recommended every 4-6 weeks, and not uncommonly 8-12 weeks is required for complete resolution. Success rates are in my experience somewhat less than 50%, and I suspect failure occurs because of the plug containing a high percentage of compacted keratinocytes to wax. There is no chemical cleaning activity that is going to be effective in these cases – they will need physical removal.









Summary

Successful therapy requires

- 1. Successful drug penetration
- 2. Correct selection of antimicrobials
- 3. Normalisation of the ear canal

Treatment failure is most commonly related to the failure of drug penetration due to excessive exudate in the ear canal and inadequate cleaning.

Ear cleaning under anaesthesia

- PAW Gentle Ear Cleaner often helps remove exudate better and faster where ear drums are intact (though not in macerated ears)
- For conservative treatment of ceruminoliths, PAW Gentle Ear Cleaner used twice weekly followed by a more aqueous cleaner may be effective as a sole therapy.

Recurrent otitis externa and the use of topical glucocorticoids



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What is the role of topical glucocorticoids in the prevention of recurrent otitis externa?

Recurrent episodes of otitis externa can be associated with multiple underlying problems including foreign bodies, recurrent wetting and ear canal anatomical abnormalities. However, the most common underlying trigger for recurrent otitis externa is underlying allergies, especially atopic dermatitis and adverse food reactions.⁴

The reasons for this are multiple, and include decreased skin barrier function (allowing better penetration of microbes, microbial toxins and allergens), increased microbial adhesion to skin cells, reduced innate immune responses, and increased inflammation in the ear canal wall. These changes to the otic microenvironment favour overgrowth of normal ear flora (typically *Staphylococcus pseudintermedius and/or Malassezia pachydermatis*) leading to recurrent infection. Secondary implantation (e.g. from scratching) of environmental bacteria into this moist environment followed by antibiotic selection pressure starts the progression towards more complex infections (e.g. *Pseudomonas* spp).

In clinical practice at the Animal Skin and Ear Specialists we have found that once weekly topical glucocorticoids are usually adequate to control relapse of otitis externa in most allergic dogs without ear canal anatomical abnormalities. I have not seen maceration as a consequence of once weekly long term therapies, though have seen it occasionally in some cases requiring twice weekly therapy. Other side effects, aside from occasional focal hair loss at the base of the pinnae and focal comedones on the tragus, have not been noted in my experience in dogs. Cats are a little more susceptible to topical glucocorticoid side effects including acquired 'floppy' pinnae.

We typically use 0.1% mometasone lotion, 0.05-0.1% dexamethasone or hydrocortisone aceponate 0.0584%. Critical to success is ensuring the ear canal is as normal as is possible prior to commencement of therapy. Starting prevention therapies prematurely following treatment of otitis markedly increases the risk of their failure. In previous years commercial otic formulations have been used to

achieve this but with the rising prevalence of methicillinresistant *S. pseudintermedius* in companion animals, routine preventative use of systemic or topical antibiotics is to be avoided where possible.

Glucocorticoids have been used anecdotally added to ear cleaners and while efficacy has not been assessed clinically they should be effective. Clinicians should remain aware of maceration as a risk especially with twice weekly or greater use (the latter of which is not recommended) long term, and that infection may recur secondary to maceration.

If an ear continues to relapse with otitis despite appropriate preventative therapies, then reassessment of both the ear canal and the underlying diagnosis is warranted because

- exudate in the deep ear canal can prevent penetration of topical glucocorticoids
- exudate in the deep ear canal can entrap otherwise undiagnosed infection
- topical glucocorticoids are going to be most effective where allergies are the underlying trigger for the recurrent otitis

Summary

- The most common underlying trigger for recurrent otitis is underlying allergies.
- Topical glucocorticoids are effective for prevention of allergic otitis because they control the early steps of inflammation which would otherwise progress to create a microenvironment suitable for microbial overgrowth and subsequent infectious otitis.
- Once weekly topical glucocorticoids are often adequate to control relapse of otitis externa in allergic dogs prone to recurrent otitis when administered to a clean and non-infected ear canal.
- If the ear continues to relapse, reassessment of the ear canal and the diagnosis are warranted.

PAW Gentle Ear Cleaner + Dexamethasone stability (0.2mg/ml) ^{2, 3, 5, 3}

Method:

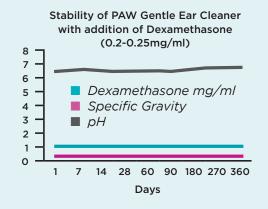
Stored at 25°C/60% relative humidity for 12 months. One bottle was allocated for each time point assigned in the testing schedule.

The product was examined at Day 1, 7, 14, 28, 60, 90, 180 and 360 days for organoleptic properties (appearance), physical properties (specific gravity, pH) and dexamethasone content.

Results:

The organoleptic properties of the formulation remained consistent over the 12 months, with no notable changes in specific gravity or pH.

Dexamethasone was stable in PAW Gentle Ear Cleaner after 12 months storage at 25°C/60% relative humidity in 120ml HDPE bottles.



HOW TO CHOOSE WHETHER PAW GENTLE EAR CLEANER IS RIGHT FOR YOUR CASE

Does the patient potentially have wet ear canals following swimming or bathing?



Choose an alcohol based ear solution soon after to speed up drying

Does the patient likely have allergic otitis leading to recurrent episodes of OE?



Consider weekly PAW Gentle
Ear Cleaner combined with
dexamethasone as a preventative
once infections are controlled

Is there evidence of a failure of self cleaning?

- Accumulation of debris and cerumen (mild waxy and dirty ear canals in the absence of infection on cytology)
- Patient prone to recurrent ceruminoliths (ear wax plugs)



YES

The ears appear healthy and clean. No ear cleaner is required!

Consider routine weekly to fortnightly PAW Gentle Ear Cleaner if ceruminoliths are not present to maintain a clean ear, or twice weekly PAW Gentle Ear Cleaner followed by an aqueous, lactic acid-containing cleaner if ceruminoliths are present. (Reassess after 6-8 weeks and consider an ear flush under GA if ceruminoliths are still evident.)

Does the patient have an ear infection with no significant exudate?

Does the patient have an ear infection with ceruminous to mildly purulent exudate?

Does the patient have an ear infection with excessive purulent exudate and rods on cytology?

No ear cleaner is required





Consider PAW Gentle Ear Cleaner to reduce exudate (either conscious or under GA) prior to application of an appropriate multipurpose otic preparation based on cytology A GA and flush to clean and debulk infection and assess tympanic membrane integrity is strongly recommended. Following that choose an alkalinising/antiseptic ear cleaner in combination with appropriate topical antibiotics

Does the patient have significant otic maceration or a ruptured tympanic membrane?



PAW Gentle Ear Cleaner is not indicated

Introducing the PAW Practitioner Range Developed for vets, by vets.



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