

# actea™

## OTO

Use of ACTEA™ OTO topical product  
as adjuvant therapy for otitis externa  
in dogs: preliminary study in 10 patients

### RESEARCHERS

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## Premise

Erythematous and ceruminous Otitis externa occurs frequently in the course of various diseases, such as canine atopic dermatitis, adverse reactions to food, hypothyroidism, keratinisation defects etc. When the perpetrating causes and factors are not identified and/or removed, it often becomes recurring or chronic.

- ✓ In cases of otitis externa, the lipid component of the earwax decreases and there is an increase in relative humidity and pH.
- ✓ Ear inflammation is accompanied by the decrease in the lipid component of earwax and an increase in the number of bacteria. In acute phases, Staphylococci (gram-positive coccoid bacteria) prevail, while chronic phases favour the presence of infections by gram-negatives as well as opportunistic fungi such as *Malassezia*.
- ✓ The use of topical agents that maintain normal pH of the ear and carry out efficient antimicrobial activity is the basis to properly manage recurring ear infections and allow the use and overuse of topical and systemic antibiotics to be limited.

## Purpose of the study

- To assess whether any changes occur to the ear bacterial and fungal population during use of the **ACTEA™ OTO** topical product under study.
- To assess whether there is a decrease in ear itching through assessment with analogue itching scale submitted to the owner.
- To assess - through clinical scores attributed by the experimenting veterinarian - whether there are objective variations in the erythema and lichenification of the pinna and ear canal in dogs treated with the **ACTEA™ OTO** topical substance.

## Materials and Methods

The clinical study was conducted according to “*good clinical practice*” [Gazzetta Ufficiale (G.U.) (Official Gazette) no. 289; 10 dicembre 1996, 47–53] and subject to informed consent of the owner.

### Selection of the animals

Ten dogs suffering from erythematous and ceruminous otitis were included, that fell under the following inclusion criteria:

- ✓ more than three otitis episodes in the last 18 months
- ✓ otoscopy compatible with erythematous and ceruminous otitis
- ✓ cytology compatible with bacterial overgrowth (> 10 bacteria at 40x) and/or of *Malassezia* (>10 yeasts at 40x), presence of keratinocytes and absence of neutrophilic granulocytes, macrophages.

In the event of intense pain or difficulty in handling, use of oral prednisone 1 mg/kg/os a day was allowed for three days, suspending for two days prior to the inclusion visit. Dogs who had received systemic or topical antibiotic, antifungal ear therapies, including ear cleaning solutions, in the last 7 days could not be included. Dogs could not be included in the study a priori if they presented otitis from: parasitic causes (otodectic mange, demodectic mange); foreign bodies; neoplastic causes (e.g. tumours or polyps occluding the ear canal); chronic idiopathic hyperplastic polypoid, purulent otitis or otitis media.

### Clinical-instrumental assessments at: V1 (selection visit), V7, V14, V21

- 1) Otoscopy and assessment of the pinna and ear canal conditions
- 2) Assessment of pinna conditions (erythema, lichenification, signs of self-trauma), assessment scale (MODIFIED CADESI SCORES)
- 3) Cerumen cytology
- 4) Cerumen sampling for bacteriological examination, when deemed necessary
- 5) Assessment through analogue itching score (VAS) by the owner
- 6) Reporting causes predisposing to otitis, if identified and/or already known

### Statistical analysis

Statistical analysis was carried out with SPSS software (version 19; SPSS Inc., Chicago, IL, USA). The data were analysed with the Shapiro-Wilk and Kruskal-Wallis tests if with normal distribution; otherwise with the Friedman test for data not normally distributed to repeated analysis. Data with p-value  $\leq 0.05$  were considered statistically significant.

## Outcome

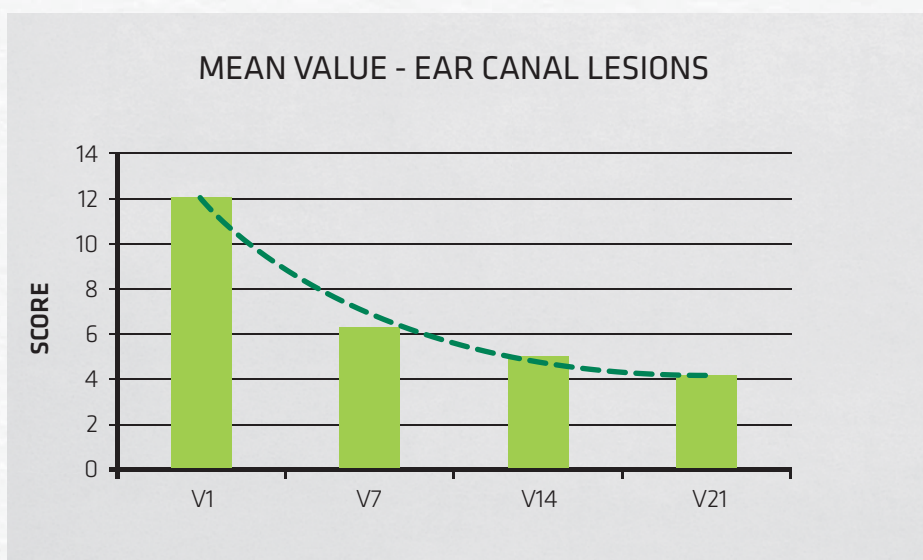
All included animals completed the study. No adverse reactions to the product occurred in any patients and the owners rated its application easy.

### Otoscopy and assessment of the pinna and ear canal conditions

Otoscopy assessment (Heine Otoscope) of the ear canal to check for cerumen, erythema, ulcers and erosions, assigning the following lesion score:

0: none      1: slight      2-3: moderate      4-5: severe

A total score\* was then calculated for each subject, entered in the table for each visit (V1, V7, V14, V21), which was then entered in the graph below as mean group value;



### Remarks

There was a noticeable decrease in cellularity already after the first 7 days, represented by exfoliated keratinocytes in the cytological sample of coccoid and rod-shaped bacterial load, as well as a decrease in *Malassezia*, which was maintained until day 21 of treatment. On the whole, there was a rapid and progressive improvement in the ear canal conditions during treatment with **ACTEA™ OTO**, and a significant reduction in microbial proliferation. The statistical analyses show statistically significant differences for all assessed parameters between V1, V7, V14, and V21.

\*sum of the score related to the four clinical parameters examined

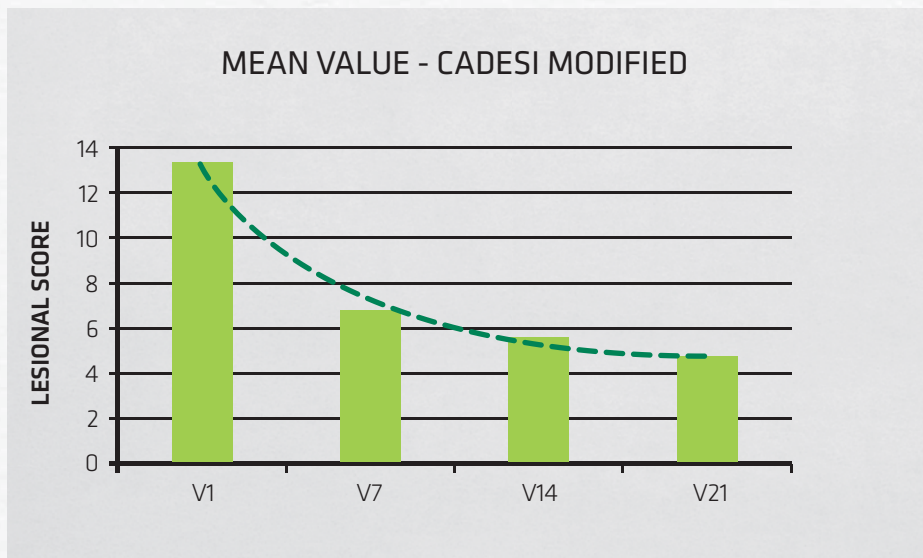
## Assessment of pinna conditions (MODIFIED CADESI)

A MODIFIED CADESI was used, especially adapted to the assessment of dermatological lesions (erythema, lichenification, excoriation, signs of self-trauma) localised in the peri-auricular area of the head and pinna.

The following lesion score was attributed:

0: none      1: slight      2-3: moderate      4-5: severe

A total score\* was then calculated for each subject, entered in the table for each visit (V1, V7, V14, V21), which was then entered in the graph below as mean group value;



### Remarks

There was a noticeable improvement in pinna lesions already after the first 7 days, with a 50% decrease in the lesion score, which was maintained until day 21 of treatment. On the whole, there was a rapid and progressive improvement in the observed parameters: erythema, lichenification, excoriation and self-induced alopecia.

**The reduction in the CADESI score turned out to be statistically significant ( $p=0.000$ ) between V1, V7 and V14, while the difference between V14 and V21 was not statistically significant.**

## Cerumen cytology

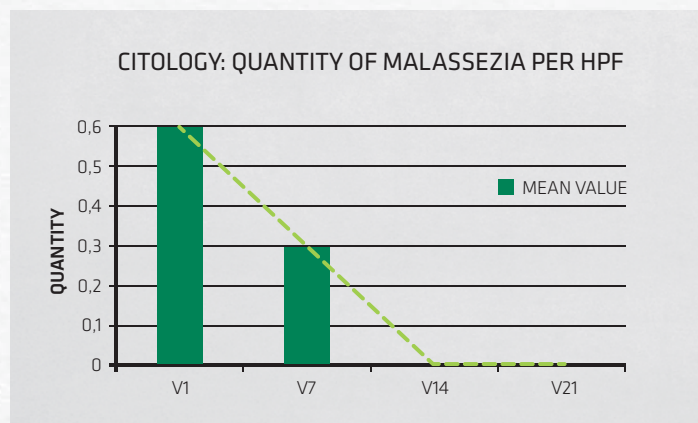
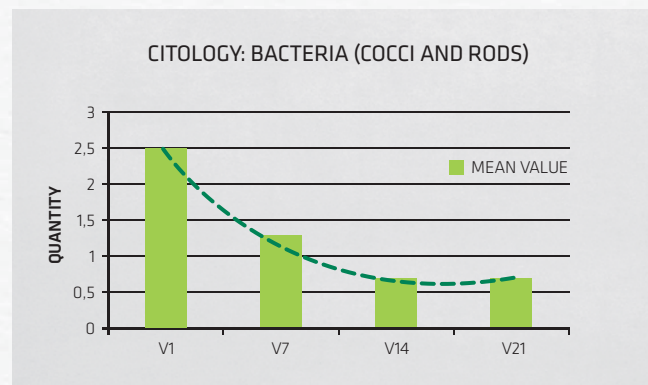
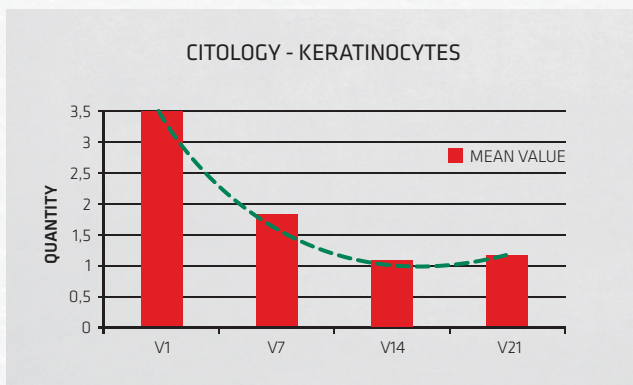
At the time of the inclusion visit and subsequent examinations (V7, V14, V21), deep sampling was performed in the ear canal with sterile cotton swab, stained with quick stain (Diff Quick™) and examined at 40x magnification to count the keratinocytes (nucleated and non) of coccoid and rod-shaped bacteria and of *Malassezia*.

### Score used for manual keratinocyte count

1: < 5HPF      2: 5-10HPF      3: 10-20 HPF      4: > 20 HPF

### Score used for manual bacteria and *Malassezia* count

1: 10-20 HPF      2: 20-30 HPF      3: 30-40 HPF      4: > 40 HPF



### Remarks

There was a noticeable decrease in cellularity already after the first 7 days, represented by exfoliated keratinocytes in the cytological sample of coccoid and rod-shaped bacterial load, as well as in *Malassezia*, which was maintained until day 21 of treatment.

**On the whole, there was a rapid and progressive improvement in the ear canal conditions during treatment with ACTEA™ OTO, and a significant reduction in microbial proliferation.**

**The statistical analyses show statistically significant differences for all assessed parameters among V1, V7, V14, and V21.**

## Conclusions

On the basis of the data obtained, the **ACTEA™ OTO** otological product under investigation proves to have **good efficacy in reducing the clinical signs of ceruminous otitis**, restoring the physiological conditions of the ear canal and the normal microbial flora. The parameters associated to modified CADESI also significantly improve with a decrease in erythema, alopecia, excoriation and lichenification. The most significant improvements always occurred between V1 and V7, whereas they remained stable, albeit with an improving trend, between V7 and the final visit V21.

Furthermore, **ACTEA™ OTO** showed **remarkable effectiveness in removing cerumen and cellular debris from the outer ear canal**, already just a few minutes (10 min) after application.



**ACTEA™ OTO** may be considered an **effective treatment for external erythematous and ceruminous otitis** characterised by mixed microbial overgrowth, especially in cases of **recurrent otitis during atopic dermatitis, thus avoiding the use of topical antibiotic, antifungal and anti-inflammatory therapy.**

The use of **ACTEA™ OTO** had no occurrence of **any localised allergic reactions** and was rated by all owners as **satisfying in terms of results and easy to use.**



**NEW**

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**OTO**

with



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