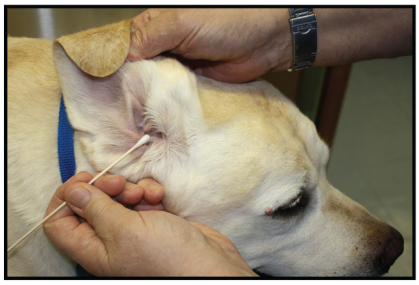
Ketocort® Otic - Instructions

KETOCORT® OTIC Gel - A hydrogel with Ketoconazole, USP and Hydrocortisone acetate, USP

Please read ALL the directions carefully and thoroughly before proceeding.

"Clean, Dry, then Apply"

1. Examine dog or cat ears for otitis.
2. Perform cytology to confirm a Malassezia yeast infection.
3. Using a cerumenolytic (like dioctyl sodium sulfosuccinate, DSS) thoroughly clean the wax from the ear(s) by an ear flushing procedure.



4. Dry the ear canals using suction or cotton wadding.
5. Attach the supplied applicator tip to the **KETOCORT®** luer lock syringe. Gently insert the applicator tip into the ear canal as deep as is comfortable for the patient.

6. Slowly push the plunger to instill the liquid medication into the ear canal. Continue instilling until the medication becomes visible around the syringe and applicator. Withdraw the syringe and applicator.

7. If the otitis is bilateral, change applicator tip before instilling gel into second ear of the same patient.
8. **KETOCORT® OTIC** gel will thicken as it warms to body temperature. Comfort the dog or cat (rub the ears) to prevent head shaking for a minute or two and to allow complete gelation of the solution.
9. Recheck patient in 7 days and reapply product if any yeasts persist.

Clinical Trial Results

Twenty-three ears were studied in this trial. A successful outcome of trial was determined to be a Malassezia score of 0 or 1. Distribution of Malassezia and itch scores in the enrolled dogs and the outcome of the study are provided below in tables 1 and 2, respectively.

Table 1: Distribution of Malassezia and Itch grades.

Day	Malassezia Grade (number of ears)				Itch Grade (number of ears)		
	< 2	2	3	4	< 3	3	4
0	0	2	6	15	0	1	22
7	18	1	1	3	19	3	1
14	14	0	2	7	19	1	3

Table 2: Outcome of the Study.

Day	Outcome (Mean ± standard deviation)			
	Malassezia Score	Success Rate (%)	Itch Score	Success rate (%)
0	3.57 ± 0.66	---	3.78 ± 0.85	---
7	0.83 ± 1.47*	78	1.83 ± 0.98*	83
14	1.74 ± 1.74^{ns}	61	1.57 ± 1.20^{ns}	83

*$p < 0.05$ when compared with the corresponding 1st visit value using a two-tail Student t-test.
$^{ns}p > 0.05$ when compared with the corresponding 2nd visit value using a two-tail Student t-test.
ns = not statistically significantly different.

Conclusions:

It can be concluded from the above study that **KETOCORT® OTIC** was not only successful in reducing the yeast count and itch scores with one dose but also was effective in keeping the counts reduced up to day 14. Ketoconazole and hydrocortisone in **KETOCORT® OTIC** were effective at reducing Malassezia and severe pruritus with significant relief from itching. This could be a direct effect of the hydrocortisone or it could be from the reduction in the pruritus from the reduction of the Malassezia yeast numbers in the ears. The data from this clinical trial shows that a single infusion of this topical formulation is beneficial in treating Malassezia otitis externa and provides comfort from pruritus for up to 14 days. Complete study information available at ***ketocortotic.com***.

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