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Aurizon ear drops, suspension

Species:	Dogs
Therapeutic indication:	Pharmaceuticals: Antimicrobials: Topical preparations: Ear/eye/nose
Active ingredient:	Clotrimazole, Dexamethasone, Marbofloxacin
Product:	Aurizon ear drops, suspension
Product index:	Aurizon
Incorporating:	

Presentation

Homogenous beige to yellow oily suspension. Each ml contains marbofloxacin 3mg, Clotrimazole 10mg and Dexamethasone (as acetate) 0.9mg as active substances. It also contains Propyl Gallate 1mg.

Uses

For use in dogs for the treatment of otitis externa of both bacterial and fungal origin – respectively due to bacteria sensitive to marbofloxacin, and fungi sensitive to clotrimazole. Use of the product should be based on susceptibility testing.

The preparation contains three active ingredients:

- Marbofloxacin: a synthetic anti-infectious bactericidal agent belonging to the fluoroquinolone family that acts by inhibiting DNA gyrase. It exhibits a very broad spectrum of activity against Gram-positive bacteria (in particular *Staphylococcus intermedius*) and against Gram-negative organisms (*Pseudomonas aeruginosa*, *Escherichia Coli* and *Proteus mirabilis*).
- Clotrimazole: an anti-fungal agent that belongs to the imidazole family and which acts by causing changes in membrane permeability, allowing intracellular compounds to leak from the cell and thus inhibiting cellular molecular synthesis. It exhibits a wide spectrum of activity and is aimed, in particular at *Malassezia pachydermatis*.
- Dexamethasone acetate: a synthetic glucocorticoid exhibiting anti-inflammatory and anti-pruritic activity.

Dosage and administration

Shake well before use.

Apply ten ear drops into the ear once daily for 7 to 14 days. After 7 days of treatment, the veterinary surgeon should evaluate the necessity to extend the treatment another week.

One drop of the preparation contains 71 microgram marbofloxacin, 237 microgram clotrimazole and 23.7 microgram dexamethasone acetate.

After application, the base of the ear may be massaged briefly and gently to allow the preparation to penetrate to the lower part of the ear canal. When the product is intended for use in several dogs, use one cannula per dog. Avoid the introduction of contamination during use.

Contra-indications, warnings, etc

Withdrawal periods

Not applicable

Do not administer to dogs suffering from perforation of the tympanic membrane,

Do not administer to dogs with known sensitivity to any of the ingredients,

Do not administer to pregnant or lactating bitches,

Usual adverse reactions associated with corticosteroid drugs may be observed (changes in biochemical and haematological parameters, such as increase of alkaline phosphatase and of aminotransferase, some limited neutrophilia)

Prolonged and intensive use of topical corticosteroid preparations is known to trigger local systemic effects, including suppression of adrenal function, thinning of the epidermis and delayed wound healing.

On rare occasions, the use of this product may be associated with deafness, mainly in elderly dogs and mostly of a transient nature.

Heavy reliance on a single class of antibiotic may result in the introduction of resistance in a bacterial population. It is prudent to reserve fluoroquinolones for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly to other classes of antibiotics.

Before treating with the product, the integrity of the tympanic membrane must be verified.

The external ear canal should be meticulously cleaned and dried before treatment.

Changes in biochemical and heamatological parameters (such as increase of alkaline phosphatase), aminotransferase, some limited neutophilia, eosinopenia, lymphopenia) are observed with three fold the recommended dosage: such changes are not serious and will reverse once treatment has stopped.

Operator warnings

Wash hands carefully after applying product. Avoid contact with eyes. If the product splashed the eye accidentally, rinse with copious amounts of water.

Persons with known hypersensitivity to compounds in the product should avoid any contact with the product.

Pharmaceutical precautions

Do not store above 30°C

After opening, use the product within 2 months. Any unused product or waste material should be disposed of in accordance with national requirements.

Legal category

Legal category: POM-V

Packaging quantities

Boxes containing: 10ml bottle and cannula and 20ml bottle and 2 cannulae.

Further information

Aurizon does not contain an antimicrobial preservative.

Pharmacokinetics studies in dogs at the therapeutic dosage have shown that: Marbofloxacin plasma concentrations peak at 0.06 µg/ml on the 14th day of treatment.

Marbofloxacin bonds weakly to plasma proteins (< 10% in dogs) and is eliminated slowly, mainly in the active form, over 2/3 in urine and over 1/3 in faeces. Clotrimazole absorption is extremely poor (plasma concentration < 0.04 mg/ml).

Dexamethasone acetate plasma concentration reaches 1.25 ng/ml on the 14th day of treatment. Dexamethasone resorption is not increased by the inflammatory process induced by otitis.

Marketing Authorisation Number

UK: Vm 08007/4085

Significant changes

GTIN

GTIN description:	Aurizon 10ml
GTIN:	03605877139166
GTIN description:	Aurizon 20ml
GTIN:	03605877139241