



# Product Information

## AURIZON®

### Description:

Marbofloxacin 3 g/L, Clotrimazole 10 g/L, Dexamethasone acetate 0.9 g/L.

Low density polyethylene bottle. Low-density polyethylene nozzle. Threaded polypropylene cap. PVC cannula.

### Presentation:

Box containing 1 x 10ml bottle and 1 cannula.  
Box containing 1 x 20ml bottle and 1 cannula.

### Indications:

In dogs: Treatment of otitis externa of both bacterial and fungal origin – respectively due to bacteria sensitive to marbofloxacin and fungi especially *Malassezia pachydermatis* sensitive to clotrimazole.

This product should be used based on susceptibility testing.

### Warnings and Contra-indications:

The use of Aurizon® in dogs with perforation of the tympanic membrane has not been evaluated.

Aurizon® is contra-indicated to dogs with known hypersensitivity to any of the ingredients.

The safety of Aurizon® in pregnant or lactating bitches has not been established.

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

Prolonged and intense use of tropical corticosteroid preparations is known to trigger local and systemic effects, including suppression

of adrenal function, thinning of the epidermis and delayed wound healing.

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

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

### Details of use:

Pharmacodynamic properties:

The preparation combines three active ingredients:

Marbofloxacin, a synthetic bactericidal agent belonging to the fluoroquinolone family that acts by inhibiting DNA gyrase. It exhibits a broad spectrum of activity against Gram-positive (e.g. *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*:

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## AURIZON® (cont)

Dexamethasone acetate, a synthetic glucocorticoid exhibiting anti-inflammatory and anti-pruritic activity.

Pharmacokinetic properties:

Pharmacokinetics studies in dogs at the therapeutic dosage have shown that:

Marbofloxacin plasma concentrations peak at 0.06ng/mL on the 14<sup>th</sup> day of treatment.

Marbofloxacin binds 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 <0.04ug/mL).

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

### Dosage:

Shake well before use.

Apply ten 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 71ug marbofloxacin, 237ug clotrimazole and 23.7ug 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 cannulae per dog,

Changes in biochemical and haematological parameters (such as increase of alkaline phosphatase, aminotransferase, some limited neutrophilia, eosinopenia, lymphopenia) are

observed with three fold the recommended dosage; such changes are not serious and will reverse once the treatment has stopped.

### Withholding Period:

N/A

### Approved Shelf Life of Formulated Product:

18 months from date on manufacture. In use stability 2 months from opening.

Registered pursuant to the ACVM Act 1997,  
NoA10031  
**RESTRICTED VETERINARY MEDICINE**  
Aurizon®  
For Animal Treatment Only



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