

**Aurizon<sup>®</sup>**, JUST A SIMPLE ONCE-A-DAY DOSE  
FOR RAPID CLINICAL SUCCESS



## Veterinary Guide to Aurizon<sup>®</sup>



# Vetoquinol & Aurizon®

Leading the way forward  
in the treatment of  
otitis externa

With the launch of Aurizon®, Vetoquinol brought a unique option for the treatment of otitis externa to you the vet.

Using Aurizon® you can offer your patients and their owners high cure levels, the convenience of once-a-day application, and the confidence of fast pain relief.

***“Fast pain relief,  
high clinical cure  
levels, once daily  
application”***



# Aurizon®

The technology that delivers the benefits

**The active ingredients:  
Marbofloxacin,  
Clotrimazole,  
Dexamethasone**

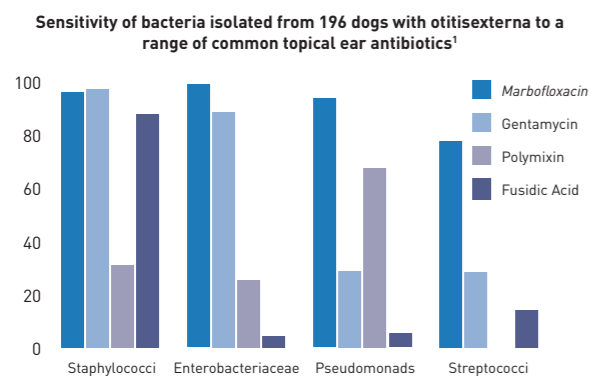
## Marbofloxacin

Used exclusively in veterinary medicine, *marbofloxacin* is a third generation fluoroquinolone and is the first molecule in its class to be licensed for topical use in otitis externa. In the form of Marbocyl P tablets and Marbocyl SA injection, *marbofloxacin* is already a well known and trusted antibiotic.

### Key points on *marbofloxacin*

- *Marbofloxacin* has a bactericidal action that destroys DNA at the heart of the bacterial cell.
- Allows you to reduce reliance on topical aminoglycoside antibiotics.
- Uniquely also available for systemic use. (Marbocyl P (palatable) Tablets & SA Injection)
- When used systemically the safety profile compares well to that of many of the aminoglycoside antibiotics frequently used in other ear preparations.

The broad spectrum of *marbofloxacin* affords the level of confidence you need in Otitis externa:



## Clotrimazole

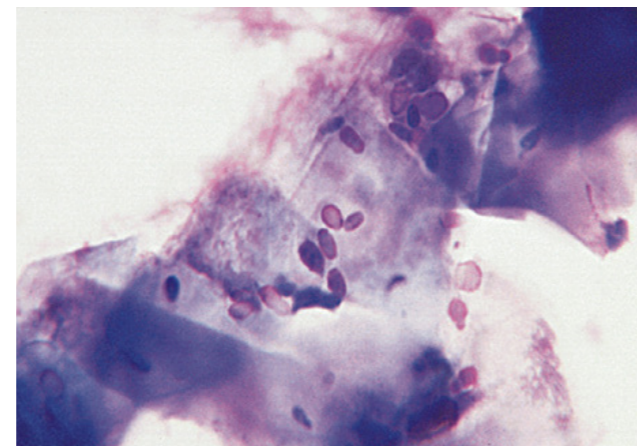
Antifungal/anti-yeast activity is required in many cases of otitis externa. *Clotrimazole* delivers the performance you need.

### Key points on *Clotrimazole*

- *Clotrimazole* is a well-researched antifungal agent.
- In a number of studies, *Clotrimazole* has demonstrated superior activity against *Malassezia pachydermatis* compared with nystatin and miconazole<sup>3,4</sup>

Sensitivity of 42 strains of *Malassezia pachydermatis* to a range of commonly used antifungal agents<sup>3</sup>

Antifungal Agent	MIC <sub>90</sub> (µg/ml)	% resistant strains
Clotrimazole	5	0
Nystatin	40	7
Miconazole	20	2



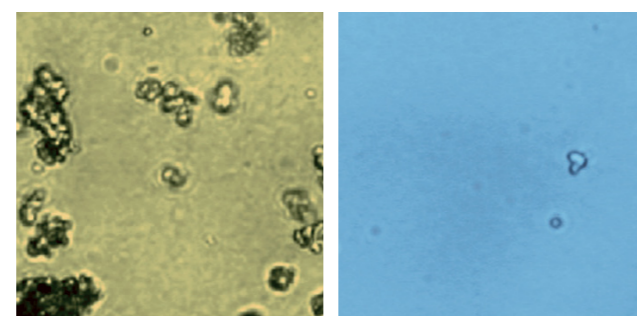
*Malassezia pachydermatis*, isolated in up to 82% of otitis externa cases in dogs<sup>4</sup>

## Dexamethasone

Anti-inflammatory activity is vital for a successful outcome in many cases of otitis externa. As a proven and trusted anti-inflammatory, *Dexamethasone* is the third and final ingredient of Aurizon®.

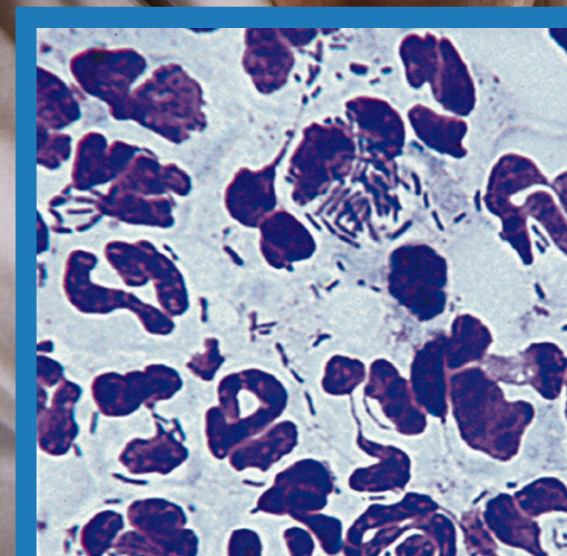
### Key points on *Dexamethasone*

- Helps break the destructive cycle of pain, irritation and self trauma.
- Reduces inflammation, which is vital if the normal architecture of the ear is to be restored.



Conventional suspension

Aurizon® micronized suspension



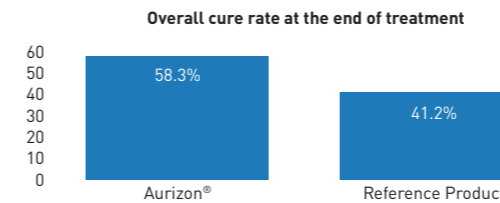
*Marbofloxacin* shows superior activity against *Pseudomonas spp.* Independent researchers<sup>2</sup> and Vetoquinol's Epidemiosurveillance Scheme<sup>1</sup> have monitored sensitivity levels and confirm activity against *Pseudomonas spp.* has been maintained.



## Clinical cure rates

With Aurizon<sup>®</sup>, excellent efficacy means high clinical cure rates.

In a randomised, comparative, blinded study using 15 centres throughout Europe, 140 dogs with acute or subacute otitis externa showed excellent results when treated with Aurizon<sup>®</sup> <sup>1</sup>. Aurizon<sup>®</sup> was compared with a UK licensed preparation containing a combination of polymixin, miconazole and prednisolone. Both products were given according to their approved dosages with Aurizon<sup>®</sup> being used just once daily and the reference product twice daily. If not considered cured after 7 days, a further 7 days of treatment was given. No additional treatment other than ear cleaning was permitted.



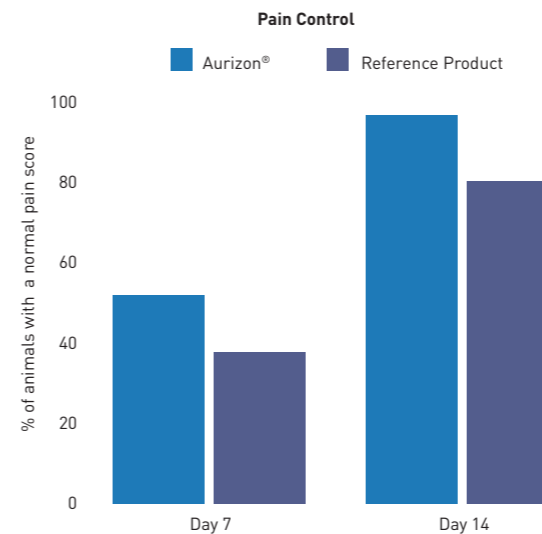
The statistically significant benefits seen in the Aurizon<sup>®</sup> group when compared with those treated with the reference product were:

- Superior overall clinical response rate
- Superior pain control
- Reduction in amount of pus produced

## Fast pain relief

With Aurizon<sup>®</sup>, excellent efficacy in otitis also means fast pain relief

In the same comparative study<sup>1</sup>, Aurizon<sup>®</sup> treated dogs were shown to be in significantly less pain than those treated with the reference product.



# Aurizon<sup>®</sup>

The technology that delivers the benefits

## Once daily

Aurizon<sup>®</sup> for otitis: one of the few occasions when one is better than two.

The frequency of application is an important consideration in choosing ear treatments. With Aurizon<sup>®</sup> you get the high cure levels and fast pain relief you demand but you can also offer your clients the convenience of once-a-day application:

The potential benefits are there for everybody:

- **For the owner**  
Reduced work and increased ease of use
- **For your patient**  
Less frequent handling of painful ears
- **For you**  
Increased confidence in owner compliance and increased owner satisfaction

Put the first treatment in during the consultation and by the check-up in 1 week your client need only have applied Aurizon<sup>®</sup> 6 times (Compared with 13 for the other leading products).

## Further benefits

Aurizon<sup>®</sup> also offers other features to aid ease of application and increase effectiveness

- Soft cannula to reduce pain on application
- See-through cannula to make application easier for owners
- Low viscosity, micronised, suspension improves spreading of Aurizon<sup>®</sup> throughout the ear canal
- Ceruminolytic base to aid break-up of wax

1. Rougier S, et al, (2005) A comparative study of two antimicrobial/anti-inflammatory formulations in the treatment of canine otitis externa. Vet Dermatol. Oct;16(5):299-307.

# PRESCRIBING AND USE INFORMATION

## Aurizon® EAR DROPS SUSPENSION - TREATMENT FOR OTITIS EXTERNA IN DOGS – 20 ML MARBOFLOXACIN – CLOTRIMAZOLE – DEXAMETHASONE ACETATE

### ACTIVE CONSTITUENTS

Each mL contains 3 mg *marbofloxacin*, 10 mg *clotrimazole* and 1 mg *dexamethasone acetate*.

For the treatment of otitis externa in dogs of both bacterial and fungal origin respectively due to bacteria sensitive to *marbofloxacin* and fungi, especially *Malassezia pachydermatis*, sensitive to *clotrimazole*.

### PHARMACOLOGY

**Marbofloxacin** is 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 bacteria (e.g. *Staphylococcus intermedius*) and against Gram-negative organisms (*Pseudomonas aeruginosa*, *Escherichia coli* and *Proteus mirabilis*).

**Pharmacokinetic** 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* binds weakly to plasma proteins (<10% in dogs) and is eliminated slowly, mainly in the active form, with over 2/3 being excreted in the urine and 1/3 in the faeces.

**Clotrimazole** is a broad-spectrum antifungal agent that is used for the treatment of dermal infections caused by various species of pathogenic dermatophytes and yeasts. The primary action of *clotrimazole* is against dividing and growing organisms. In vitro, *clotrimazole* exhibits fungistatic and fungicidal activity against isolates of *Trichophyton rubrum*, *Trichophyton mentagrophytes*, *Epidermophyton floccosum*, *Microsporum canis*, *Candida spp.*, and *Malassezia pachydermatis*.

Resistance to *clotrimazole* is very rare among the fungi that cause superficial mycosis. In studies on the mechanism of action, the minimum fungicidal concentration of *clotrimazole* caused leakage of intracellular phosphorus compounds in the ambient medium with concomitant breakdown of cellular nucleic acids and accelerated potassium efflux. These events began rapidly and extensively after addition of the drug. *Clotrimazole* is very poorly absorbed following dermal application (plasma concentration <0.04 µg/mL).

**Dexamethasone acetate** is a synthetic glucocorticoid exhibiting anti-inflammatory and antipruritic activity. Topical corticosteroids can be absorbed from normal intact skin. Once absorbed through the skin, topical corticosteroids are handled through the pharmacokinetic pathways similar to systemically administered corticosteroids. *Dexamethasone acetate* plasma concentrations reached

1.25 mg/mL on the 14th day of treatment. *Dexamethasone* absorption was not increased by the inflammatory process induced by otitis.

### INDICATIONS

Aurizon® is indicated for the treatment of otitis externa in dogs of both bacterial and fungal origin respectively due to bacteria sensitive to *marbofloxacin* and fungi, especially *Malassezia pachydermatis*, sensitive to *clotrimazole*.

### DIRECTIONS FOR USE

#### Restraint:

**DO NOT USE** in food producing animals.

**USE ONLY** in situations where sensitivity testing indicates no alternative antibiotic.

**This product is contraindicated for use in dogs with known perforation of the tympanic membrane.**

**Marbofloxacin** is contraindicated in immature dogs as it has been shown to cause arthropathy. **Marbofloxacin** is contraindicated in dogs known to be hypersensitive.

**DO NOT USE** on pregnant or lactating bitches and dogs intended for breeding purposes.

**DO NOT USE** in dogs with known hypersensitivity to any of the active constituents.

### DOSAGE AND ADMINISTRATION

#### SHAKE WELL BEFORE USE.

**Discard unused contents within two months of initial opening. When the product is intended for use in several dogs, use a single cannula for each dog.**

Thoroughly clean and dry the external ear.  
Remove foreign material, crusted and dried debris etc with a non-irritating solution.

Clip excessive hair from the treatment area. Before instilling any medication into the ear, examine the external ear canal thoroughly to be certain the tympanic membrane is not ruptured in order to avoid the possibility of transmitting infection to the middle ear as well as damaging the cochlea or vestibular apparatus from prolonged contact. Discontinue use if hearing or vestibular dysfunction is noted during treatment.

After verifying that the eardrum is intact, shake well and instil drops as follows:

- 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 for a further 7 days.
- After application the base of the ear may be massaged briefly and gently to allow the preparation to penetrate the lower part of the ear canal.

### SAFETY DIRECTIONS

**Harmful if swallowed. May irritate the eyes and the skin. Repeated exposure may cause allergic disorders. Avoid contact with eyes and skin. If product in eyes, wash it out immediately with water. Wash hands after use.**

### FIRST AID

If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131 126.

### PRESENTATION

1 x 20 mL bottle with 2 cannulae

### DISPOSAL

Dispose of empty container by wrapping with paper and putting in garbage.

### STORAGE

Store below 25°C (Air conditioning). Protect from light. Do not freeze.

APVMA Approval No. 67225/55519

### CONTRAINICATIONS AND PRECAUTIONS/SPECIAL PRECAUTIONS FOR USE SEE PACK INSERT FOR COMPLETE INFORMATION

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