

## **LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE: Outer Carton**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

AURIZON ear drops, suspension

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each ml contains:

**Active substances:**

Marbofloxacin .....3.0 mg  
Clotrimazole .....10.0 mg  
Dexamethasone .....0.9 mg  
(equivalent to dexamethasone acetate.....1.0 mg)

**3. PACKAGE SIZE**

10 ml  
20 ml  
30 ml

**4. TARGET SPECIES**

Dogs.

**5. INDICATIONS**

**6. ROUTES OF ADMINISTRATION**

Auricular use

**7. WITHDRAWAL PERIODS**

Not applicable.

**8. EXPIRY DATE**

Exp. {mm/yyyy}

Once opened use within 2 months.

**9. SPECIAL STORAGE PRECAUTIONS**

Do not store above 30°C.

**10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”**

Read the package leaflet before use.

**11. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only

**12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**13. NAME OF THE MARKETING AUTHORISATION HOLDER**

Vetoquinol SA

**14. MARKETING AUTHORISATION NUMBER**

Vm 06462/3029

**15. BATCH NUMBER**

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING**  
**UNITS: Vial Label**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

AURIZON ear drops, suspension

**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

Each ml contains:

**Active substances:**

|                                      |         |
|--------------------------------------|---------|
| Marbofloxacin.....                   | 3.0 mg  |
| Clotrimazole.....                    | 10.0 mg |
| Dexamethasone .....                  | 0.9 mg  |
| (equivalent to dexamethasone acetate | 1.0 mg) |

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

Once opened use within 2 months.

**PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:**

**PACKAGE LEAFLET**

**1. Name of the veterinary medicinal product**

Aurizon Ear Drops, Suspension

**2. Composition**

Each ml contains:

**Active substances:**

Marbofloxacin .....3.0 mg  
Clotrimazole .....10.0 mg  
Dexamethasone .....0.9 mg  
(equivalent to dexamethasone acetate.....1.0 mg)

**Excipients:**

Propyl gallate (E310).....1.0 mg

Homogenous beige to yellow oily suspension.

**3. Target species**

Dogs.

**4. Indications for use**

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.

The veterinary medicinal product should be used based on susceptibility testing results.

**5. Contraindications**

Do not use in dogs suffering from perforation of the tympanic membrane.

Do not use in cases of hypersensitivity to the active substances, other azole antifungals or fluoroquinolones, or to any of the excipient.

**6. Special warnings**

Special precautions for safe use in the target species:

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.

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

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

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Wash hands carefully after applying the veterinary medicinal product.

Avoid contact with eyes. In case of accidental contact with the eyes, rinse with copious amounts of water.

People with known hypersensitivity to the active substances or excipients should avoid contact with the veterinary medicinal product.

Pregnancy and lactation:

Do not use during pregnancy or during lactation.

Overdose:

Changes in biochemical and hæmatological 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.

**7. Adverse events**

Dogs:

|  |
|--|
| <i>Rare (1 to 10 animals / 10,000 animals treated):</i>  |
| Deafness <sup>1</sup>  |
| <i>Very rare (&lt;1 animal / 10,000 animals treated, including isolated reports):</i>  |
| Changes in biochemical and haematological parameters (such as Elevated serum alkaline phosphatase (ALP) <sup>2</sup> ; Elevated alanine aminotransferase (ALT) <sup>2</sup> ; Elevated aspartate aminotransferase (AST) <sup>2</sup> ; Neutrophilia (limited) <sup>2</sup> ), Skin thinning <sup>3</sup> |
| <i>Undetermined frequency (cannot be estimated from the available data):</i>   |
| Delayed healing <sup>3</sup> , Hypoadrenocorticism <sup>3,4</sup>  |

<sup>1</sup> Mainly in elderly dogs and mostly of a transient nature.

<sup>2</sup> Usual adverse effects of corticosteroids.

<sup>3</sup> Known adverse effects of topical corticosteroids in case of prolonged and intensive use.

#### <sup>4</sup> *Suppression of adrenal function.*

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: [adverse.events@vmd.gov.uk](mailto:adverse.events@vmd.gov.uk)

### **8. Dosage for each species, routes and method of administration**

Auricular 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 veterinary medicinal product contains 71 µg marbofloxacin, 237 µg clotrimazole and 23.7 µg dexamethasone acetate.

After application, the base of the ear may be massaged briefly and gently to allow the veterinary medicinal product to penetrate to the lower part of the ear canal.

### **9. Advice on correct administration**

Shake well before use.

When the veterinary medicinal product is intended for use in several dogs, use one cannula per dog.

### **10. Withdrawal periods**

Not applicable.

### **11. Special storage precautions**

Keep out of the sight and reach of children.

Do not store above 30°C.

Do not use this veterinary medicinal product after the expiry date which is stated on the label or carton after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 2 months.

### **12. Special precautions for disposal**

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

### **13. Classification of veterinary medicinal products**

Veterinary medicinal product subject to prescription.

### **14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES**

Vm 06462/3029

Box containing 1 x 10 ml bottle and 1 cannula.  
Box containing 1 x 20 ml bottle and 2 cannulae.  
Box containing 1 x 30 ml bottle and 3 cannulae.

Not all pack sizes may be marketed.

### **15. PID LINK (Do not print heading)**

*[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]*

Find more product information by searching for the 'Product Information Database' on [www.gov.uk](http://www.gov.uk).

### **16. Contact details**

#### Marketing authorisation holder:

Vetoquinol SA  
34 Rue de Chene Sainte-Anne  
Magny-Vernois  
70200 Lure  
France

#### Contact details to report suspected adverse events:

Vetoquinol UK Limited  
Steadings Barn  
Pury Hill Business Park  
Nr. Alderton  
Towcester  
Northamptonshire  
NN12 7LS  
United Kingdom  
Telephone: (+44) 1280 814 500

Manufacturer responsible for batch release:

Vetoquinol S.A.  
Magny-Vernois  
70200 Lure  
France

**17. Other information**

POM-V

**Pharmacodynamics**

The veterinary medicinal product 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 bacteria (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*;
- Dexamethasone acetate, a synthetic glucocorticoid exhibiting anti-inflammatory and anti-pruritic activity.

**Pharmacokinetics**

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 fæces.

Clotrimazole absorption is extremely poor (plasma concentration < 0.04 µg/ml).

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

*Gavin Hall*

Approved: 03 November 2025