

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1. Name of the veterinary medicinal product

AURIZON ear drops, suspension

### 2. Qualitative and quantitative composition

#### 1 ml of AURIZON contains:

#### Active substances:

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

#### Excipients

Propyl galate (E310).....	1.0 mg
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For a full list of excipients, see section 6.1.

### 3. Pharmaceutical form

Ear drops, suspension  
Homogenous beige to yellow oily suspension

### 4. Clinical particulars

#### **4.1. Target species**

Dogs

#### **4.2. Indications for use, specifying the target species**

- 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 product should be used based on susceptibility testing.

#### **4.3. Contraindications**

Do not administer to dogs suffering from perforation of the tympanic membrane. Do not administer to dogs with known hypersensitivity to any of the ingredients.

Do not administer to pregnant or lactating bitches.

#### **4.4. Special warnings for each target species**

None.

4.5. Special precautions for use

**i) Special precautions for use in animals**

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 product, the integrity of the tympanic membrane must be verified.

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

**ii) Special precautions to be taken by the person administering the medicinal products to animals**

Wash hands carefully after applying the product.

Avoid contact with eyes. If splashed in the eye, rinse with copious amounts of water.

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

**iii) Other precautions**

**4.6. Adverses reactions (frequency and seriousness)**

Usual adverse reactions associated with corticosteroid drugs may be observed (changes in biochemical and hæmatological 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 and 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.

**4.7. Use during pregnancy, lactation or lay**

See "Contraindications"

**4.8. Interaction with other medicinal products and other forms of interaction**

None known

**4.9. Amount(s) to be administered and administration route**

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 71µg marbofloxacin, 237µg clotrimazole and 23.7µg 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.

**4.10. Overdose (symptoms, emergency procedures, antidotes), if necessary**

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.

#### 4.11. Withdrawal period(s)

Not applicable.

### 5. Pharmacological properties

Pharmacotherapeutic group: corticosteroids and antiinfectives in combination ATC vet code QS02CA06

#### 5.1. 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 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.

#### 5.2. Pharmacokinetic particulars

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 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 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.

#### 5.3. Environmental properties

### 6. Pharmaceutical particulars

#### 6.1. List of excipients

Propyl gallate (E310),  
Sorbitan oleate  
Silica, colloidal anhydrous  
Triglycerides, medium-chain

#### 6.2. Incompatibilities

Not applicable

#### 6.3. Shelf-life

2 years.

After opening : 2 months.

**6.4. Special precautions for storage**

Do not store above 30°C.

**6.5. Nature and composition of immediate packaging**

Details of the primary packaging:

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

Presentation :

- 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

**6.6. Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate**

Any unused product or waste material should be disposed of in accordance with national requirement.

**7. Marketing authorisation holder**

VETOQUINOL S.A  
MAGNY-VERNOIS  
70200 LURE  
FRANCE

**8. Marketing authorisation number(s)**

**9. Date of the first authorisation/Renewal of the authorisation**

**10. Date of the revision of the text**

**PROHIBITION OF SALE, SUPPLY AND/OR USE.**

## BOX

### 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AURIZON ear drops, suspension

### 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml of AURIZON contains:

#### Active substances:

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

#### Excipients

Propyl galate (E310)..... 1.0 mg

### 3. PHARMACEUTICAL FORM

Ear drops, suspension

### 4. PACKAGE SIZE

- 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

### 5. TARGET SPECIES

Dogs

### 6. INDICATION(S)

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 product should be used based on susceptibility testing.

### 7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

### 8. WITHDRAWAL PERIOD

Not applicable.

### 9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

### 10. EXPIRY DATE

EXP

Shelf life after first opening the container: 2 months

**11. SPECIAL STORAGE CONDITIONS**

Do not store above 30°C.

**12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Any unused product or waste material should be disposed of in accordance with national requirement.

**13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable**

For animal treatment only

To be supplied only on veterinary prescription.

**14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"**

Keep out of the reach and sight of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

VETOQUINOL S.A  
MAGNY-VERNOIS  
70200 LURE  
FRANCE

**16. MARKETING AUTHORISATION NUMBER(S)**

**17. MANUFACTURER'S BATCH NUMBER**

## LABEL

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

AURIZON ear drops, suspension

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

Marbofloxacin ..... 3.0 mg/ml

Clotrimazole ..... 10.0 mg/ml

Dexamethasone acetate ..... 1.0 mg/ml

**3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

10 ml bottle

20 ml bottle

30 ml bottle

**4. ROUTE(S) OF ADMINISTRATION**

Auricular use.

**5. WITHDRAWAL PERIOD**

Not applicable.

**6. BATCH NUMBER**

**7. EXPIRY DATE**

EXP

**8. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only.

## PACKAGE LEAFLET

### AURIZON ear drops, suspension

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holder <and manufacturer:

VETOQUINOL S.A  
MAGNY-VERNOIS  
70200 LURE  
FRANCE

Manufacturer for the batch release:

VETOQUINOL S.A  
MAGNY-VERNOIS  
70200 LURE  
FRANCE

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

AURIZON ear drops, suspension

**3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)**

1 ml of AURIZON contains:

**Active substances:**

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

**Excipients**

Propyl galate (E310)..... 1.0 mg

**4. INDICATION(S)**

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 product should be used based on susceptibility testing.

**5. CONTRAINDICATIONS**

Do not administer to dogs suffering from perforation of the tympanic membrane. Do not administer to dogs with known hypersensitivity to any of the ingredients.  
Do not administer to pregnant or lactating bitches.

**6. ADVERSE REACTIONS**

Usual adverse reactions associated with corticosteroid drugs may be observed (changes in biochemical and hæmatological 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 and 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.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

#### **7. TARGET SPECIES**

Dogs

#### **8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION**

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 71µg marbofloxacin, 237µg clotrimazole and 23.7µg 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.

#### **9. ADVICE ON CORRECT ADMINISTRATION**

None

#### **10. WITHDRAWAL PERIOD**

Not applicable.

#### **11. SPECIAL STORAGE PRECAUTIONS**

Do not store above 30°C.

Keep out of the reach and sight of children.

Shelf life after first opening the container: 2 months.

#### **12. SPECIAL WARNING(S)**

##### **Special precautions for use in animals**

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 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 medicinal products to animals**

Wash hands carefully after applying the product.

Avoid contact with eyes. If splashed in the eye, rinse with copious amounts of water.

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

##### **Use during pregnancy, lactation or lay**

See "Contraindications"

**Interaction with other medicinal products and other forms of interaction**

None known

**Overdose (symptoms, emergency procedures, antidotes), if necessary**

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.

**13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

Any unused product or waste material should be disposed of in accordance with national requirement.

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

**15. OTHER INFORMATION**

**Pharmacodynamic properties**

The preparation combines three active ingredients:

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Dexamethasone resorption is not increased by the inflammatory process induced by otitis.

**Presentation :**

- Box containing 1 x 10 ml bottle and 1 cannula
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**Not all pack sizes may be marketed.**