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 todexamethasone	0.9	mg)

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.

4.6 Adverse 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 interactions

None known

4.9 Amounts 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 71 micrograms marbofloxacin, 237 micrograms clotrimazole and 23.7 micrograms 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 or IMMUNOLOGICAL 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 microgram/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 14^{th} day of treatment. Dexamethasone resorption is not increased by the inflammatory process induced by otitis.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

6.2 Major 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 products or waste materials derived from the use of such products

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

7 MARKETING AUTHORISATION HOLDER

Vetoquinol Ireland Limited
12 Northbrook Road
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Dublin 6
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8 MARKETING AUTHORISATION NUMBER(S)

VPA10983/042/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 2nd November 2001
Date of last renewal: 19th December 2005

10 DATE OF REVISION OF THE TEXT

September 2019