SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AURIZON VETERINARY

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Marbofloxacin	3.0 mg
Clotrimazole	10.0 mg
Dexamethasone (as acetate)	0.9 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Silica, hydrophobic colloidal	
Sorbitan oleate	
Propyl gallate	1.0 mg
Triglycerides, medium-chain	

Ear drops.
Homogenous beige to yellow suspension.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

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.
The product should be used based on susceptibility testing.

3.3 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.

3.4 Special warnings

None.

3.5 Special precautions for use

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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

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

[1] *Mainly in elderly dogs and mostly of a transient nature.*
[2] *Usual adverse effects of corticosteroids.*
[3] *Known adverse effects of topical corticosteroids in case of prolonged and intensive use.*
[4] *Suppression of adrenal function.*

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form: https://sideeffects.health.gov.il

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Do not use during pregnancy or during lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Auricular use.

Shake well before use.

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

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 medical product to penetrate to the lower part of the ear canal.

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

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QS02CA06.

4.2 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.

4.3 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 faeces.

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

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: The expiry date of the product is indicated on the packaging materials.

Shelf life after first opening the immediate packaging: 8 weeks.

5.3 Special precautions for storage

Store below 25°C.

5.4 Nature and composition of immediate packaging

10, 20 or 30-mL low-density polyethylene (LDPE) bottle with a low-density polyethylene nozzle and a threaded polypropylene (PP) cap and 1, 2 or 3 PVC cannulae in a cardboard box.

Box containing one 10 ml bottle with 1 cannula.
Box containing one 20 ml bottle with 2 cannulae.
Box containing one 30 ml bottle with 3 cannulae.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Eliezer Linevitz Ltd, Kanot Industrial Aera, Adom 6 St., P.O.B 7006, Israel

7. MARKETING AUTHORISATION NUMBER

082-47-92301-00

8. MANUFACTURER

Vetoquinol S.A.,
Magny Vernois 70200 Lure, France

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