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 UK Limited
Steadings Barn
Pury Hill Business Park
Nr Alderton
Towcester
Northamptonshire
NN12 7LS

16. MARKETING AUTHORISATION NUMBER

Vm 08007/4085

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 UK Limited
Steadings Barn
Pury Hill Business Park
Nr Alderton
Towcester
Northamptonshire
NN12 7LS

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 andmostly 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 an other 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:

- 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.

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

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

Not all pack sizes may be marketed.

Approved: 11 September 2018

D. Austin