

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Cardboard box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Otisan 3mg/ml + 10mg/ml + 1mg/ml ear drops, suspension (RMS)

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substances:

Marbofloxacin.....3.0 mg
Clotrimazole..... 10.0 mg
Dexamethasone acetate..... 1.0 mg
(equivalent to Dexamethasone0.9 mg)

3. PACKAGE SIZE

15 ml

25 ml

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Auricular use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 6 months by...

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”
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For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”
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Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

{logo name of the marketing authorisation holder}

14. MARKETING AUTHORISATION NUMBERS
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15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Vial 15 ml, 25 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Otisan ear drops, suspension (RMS)

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

Each ml contains:

Active substances:

Marbofloxacin.....3.0 mg
Clotrimazole..... 10.0 mg
Dexamethasone acetate..... 1.0 mg
(equivalent to Dexamethasone0.9 mg)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 6 months by...

{logo name of the marketing authorisation holder}