

**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 Dexamethasone .....0.9 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"**

For animal treatment only.

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

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****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 Dexamethasone .....	0.9 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}