

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Box with bottles of 60 ml**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

LEISGUARD 5 mg/ml Oral Suspension for Dogs  
Domperidone

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Each ml contains:

Domperidone	5 mg
Methyl parahydroxybenzoate (E218)	1.80 mg
Propyl parahydroxybenzoate	0.20 mg
Quinoline yellow (E104)	0.20 mg

**3. PHARMACEUTICAL FORM**

Oral suspension

**4. PACKAGE SIZE**

60 ml  
2x60 ml  
3x60 ml  
4x60 ml

**5. TARGET SPECIES**

Dogs

**6. INDICATION(S)**

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Read the package leaflet before use.

**8. WITHDRAWAL PERIOD**

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use

**10. EXPIRY DATE**

<EXP {month/year}>

Shelf-life after first opening the immediate packaging: 8 months

**11. SPECIAL STORAGE CONDITIONS**

Store in the original package.

Protect from light.

**12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable**

For animal treatment only. To be supplied on veterinary prescription.

**14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Marketing authorisation holder:

Ecuphar Veterinaria S.L.U.

C/Cerdanya, 10-12 Planta 6º

08173 Sant Cugat del Vallés

Barcelona, Spain

**16. MARKETING AUTHORISATION NUMBER(S)**

**17. MANUFACTURER’S BATCH NUMBER**

<Batch> <Lot> <BN> {number}

**PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**Label of bottle**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

LEISGUARD 5 mg/ml Oral Suspension for Dogs  
Domperidone

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

Domperidone 5 mg/ml, Methyl parahydroxybenzoate (E218), Propyl parahydroxybenzoate ,  
Quinoline yellow (E104)

**3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

60 ml

**4. ROUTE(S) OF ADMINISTRATION**

Oral use. Shake well before use. Read the package leaflet before use

**5. WITHDRAWAL PERIOD**

**6. BATCH NUMBER**

<Batch> <Lot> <BN> {number}

**7. EXPIRY DATE**

<EXP {month/year}>

**8. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

Disposal: read package leaflet  
Keep the bottle in the outer carton to protect from light.

Marketing Authorisation Holder: Ecuphar Veterinaria S.L.U.- Barcelona (Spain)