LABELLING AND PACKAGE LEAFLET

# A. LABELLING

#### PARTICULARS TO APPEAR ON THE OUTER PACKAGE

**OUTER BOX** 

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

VEYLACTIN 50 microgram/ml oral solution for dogs and cats (CZ, DE, EL, ES, HU, IT, PL, PT, SK) VEYLACTIN vet 50 microgram/ml oral solution for dogs and cats (FI, IS, NO) KELACTIN 50 microgram/ml oral solution for dogs and cats (BE, CY, FR, LU, NL, UK) KELACTIN vet 50 microgram/ml oral solution for dogs and cats (DK, SE) cabergoline

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

cabergoline 50 microgram/ml

#### 3. PHARMACEUTICAL FORM

Oral solution

#### 4. PACKAGE SIZE

7 ml

14 ml

24 ml

### 5. TARGET SPECIES

Dog and cat

#### 6. INDICATION

Read the package leaflet before use.

# 7. METHOD AND ROUTE OF ADMINISTRATION

Read the package leaflet before use.

#### 8. WITHDRAWAL PERIOD

### 9. SPECIAL WARNINGS, IF NECESSARY

Do not leave unattended filled syringes in presence of children. Read the package leaflet before use.

#### 10. EXPIRY DATE

EXP:

Shelf life after first opening: 14 days.

Once opened, use by...

# 11. SPECIAL STORAGE CONDITIONS

As packaged for sale: store in a refrigerator (2°C - 8°C).

After first opening: store below 25°C.

Store in upright position.

Keep the vial tightly closed in the outer carton in order to protect from light.

Do not freeze.

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

Disposal: read package leaflet.

# 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 SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

# 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Veyx-Pharma GmbH Söhrenweg 6 34639 Schwarzenborn Germany

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

#### 17. MANUFACTURER'S BATCH NUMBER

Lot:

# MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

**LABEL** 

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

VEYLACTIN 50 microgram/ml oral solution for dogs and cats (CZ, DE, EL, ES, HU, IT, PL, PT, SK) VEYLACTIN vet 50 microgram/ml oral solution for dogs and cats (FI, IS, NO) KELACTIN 50 microgram/ml oral solution for dogs and cats (BE, CY, FR, LU, NL, UK) KELACTIN vet 50 microgram/ml oral solution for dogs and cats (DK, SE) cabergoline

# 2. QUANTITY OF THE ACTIVE SUBSTANCE

cabergoline 50 microgram/ml

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

7 ml 14 ml

24 ml

#### 4. ROUTEOF ADMINISTRATION

Oral administration.

# 5. WITHDRAWAL PERIOD

#### 6. BATCH NUMBER

Lot:

#### 7. EXPIRY DATE

EXP:

# 8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.