ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box of 20 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Romidys 1 mg/ml solution for injection.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml of Romidys 1 mg/ml solution for injection contains:
Active ingredient
Romifidine hydrochloride 1 mg
equivalent to 0.876 mg romifidine

Preservatives
Methyl parahydroxybenzoate (E218) 1.8 mg
Propyl parahydroxybenzoate (E216) 0.2 mg

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

20 ml

5. TARGET SPECIES

Dogs and cats.

6. INDICATION(S)

Sedative for use in dogs and cats for restraint; to facilitate handling, clinical examinations, minor surgical interventions and manipulations. Premedication agent prior to the induction of general anaesthesia. For profound sedation/analgesia in dogs it may also be used with an opioid analgesic. In cats combination with ketamine provides surgical anaesthesia.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular, intravenous or subcutaneous use in dogs and for intravenous or intramuscular use in cats.
All animals should be starved for at least 12 hours prior to injection of this product.
Dosages may vary between individual animals and may depend on temperament. Painful manipulations may require the high dose level

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Read the package leaflet before use.

9. SPECIAL WARNING(S), IF NECESSARY

User warnings:
Alpha 2-adrenoreceptor agonists can cause severe adverse reactions. Accidental self injection is dangerous. Read the user warnings on the package leaflet before use.

10. EXPIRY DATE

EXP: {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.Do not freeze.

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 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 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

VIRBAC S.A.
1ère avenue - 2065 m - L.I.D.
F-06516 Carros
France

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial label of 20 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Romidys 1 mg/ml solution for injection.

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each ml of Romidys 1 mg/ml solution for injection contains:
Active ingredient
Romifidine hydrochloride 1 mg
equivalent to 0.876 mg romifidine

Preservatives
Methyl parahydroxybenzoate (E218) 1.8 mg
Propyl parahydroxybenzoate (E216) 0.2 mg

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

20 ml

4. ROUTE(S) OF ADMINISTRATION

For intramuscular, intravenous or subcutaneous use in dogs and for intravenous or intramuscular use in cats.

5. WITHDRAWAL PERIOD

Not applicable.

6. BATCH NUMBER

Batch: {number}

7. EXPIRY DATE

EXP: {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.
See the package leaflet for full instructions and user warnings.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Romidys 1 mg/ml Solution for Injection

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

VIRBAC S.A.
1ère avenue – 2065 M – L.I.D.
F-06516 Carros
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Romidys 1 mg/ml solution for injection.

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each gram contains:

Each ml of Romidys 1 mg/ml solution for injection contains:
Active ingredient
Romifidine hydrochloride 1 mg
equivalent to 0.876 mg romifidine

Preservatives
Methyl parahydroxybenzoate (E218) 1.8 mg
Propyl parahydroxybenzoate (E216) 0.2 mg

4. INDICATION(S)

Sedative for use in dogs and cats for restraint; to facilitate handling, clinical examinations, minor surgical interventions and manipulations. Premedication agent prior to the induction of general anaesthesia. For profound sedation/analgesia in dogs it may also be used with an opioid analgesic. In cats combination with ketamine provides surgical anaesthesia.

5. CONTRAINDICATIONS

Do not use in pregnant animals.
Do not use in animals suffering from diabetes mellitus.

6. ADVERSE REACTIONS

Typical adverse reactions of α_2-agonists such as bradycardia, benign reversible cardiac arrhythmia such as type I or type II atrioventricular (AV) blocks and hypotension may occur. Thermoregulatory mechanisms may be influenced, so that body temperature may increase or decrease depending upon the environmental temperature.

Occasionally animals vomit following administration (especially if recently fed). The respiratory pattern may become irregular. Cats may vomit up to 24 hours after administration of romifidine. A dose-dependent rise in blood glucose may accompany sedation in dogs and cats. Other typical side effects of α_2 -agonists such as muscle twitching and panting and salivation may be observed in dogs. Mild and transient injection site reactions have been observed after the intramuscular administration in cats. Cases of prolonged sedation and recurrence of sedation after initial recovery have been reported.

7. TARGET SPECIES

Dogs and Cats.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Do not freeze.

12. SPECIAL WARNING(S)

Special precautions for use in animals

Sedated animals should be restrained to prevent injury. Care should be taken to ensure that animals have sufficient fluid intake. Animals, which undergo prolonged sedation, should be prevented from becoming hypothermic.
Care should be taken in animals in poor health, or in cases of cardiovascular, renal, hepatic or pancreatic disease, and in animals suffering from respiratory distress. The clinical condition of cats suffering from pancreatitis should be closely monitored (see Section 5.9).

Special precautions to be taken by the person administering the veterinary medicinal product to animals

This product contains an α_2-adrenergic agonist.

In the case of accidental oral intake or self-injection, seek medical advice immediately and show the package leaflet to the doctor but DO NOT DRIVE as sedation and changes in blood pressure may occur.

Avoid skin, eye or mucosal contact.

Immediately after exposure, wash the exposed skin with large amounts of fresh water.

Remove contaminated clothes that are in direct contact with skin.

In the case of accidental contact of the product with eyes, rinse with large amounts of fresh water. If symptoms occur, seek the advice of a doctor.

If pregnant women handle the product, special caution should be observed not to self-inject as uterine contractions and decreased foetal blood pressure may occur after accidental systemic exposure.

Advice to doctors:
Romifidine is an alpha2-adrenoreceptor agonist. Symptoms after absorption may involve clinical effect including dose-dependent sedation, respiratory depression, bradycardia, hypotension, a dry mouth, and hyperglycaemia. Ventricular arrhythmias have also been reported. Respiratory and haemodynamic symptoms should be treated symptomatically.

Use during pregnancy, lactation or lay

The product should not be used in pregnant animals

Interaction with other medicinal products and other forms of interaction

The sedative effect of the product may be potentiated by other psychoactive compounds, such as tranquillisers, other sedatives or morphine-like analgesics, therefore reducing the required dose of subsequent injectable anaesthetic agents. It also potentiates the sedative effects of anticonvulsant drugs given to dogs and cats suffering from epilepsy.

Overdose (symptoms, emergency procedures, antidotes), if necessary

Dosages twice the recommended dose caused transient side effects typical of α_2-agonists such as bradycardia, benign heart arrhythmia such as type I or type II atrioventricular (AV) blocks, hypotension, decrease in body temperature, hyperglycaemia and increase in blood urea concentration.

Dogs have been administered 1.0 mg/kg romifidine HCl intravenously (10x recommended dose) daily for four weeks without serious adverse effects. Cats have been administered 600 µg as a single intramuscular dose without serious adverse effects. Undesirable adverse effects (see Section 5.4) are generally dose dependent and disappear by 24 hours after treatment. In an experimental study, pancreatitis was observed in cats after repeated intramuscular administration of the maximum therapeutic dose and of overdoses given at 2 day intervals over a period of 6 days.
In the event of anaesthetic emergency, the effects of this product can be reversed using an α_2-antagonist, such as atipamezole solution (suggested dose rate: cats-400 µg/kg bodyweight, dogs - 200 µg/kg bodyweight).

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 requirements.

14. DATE ON WICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

- Box containing 1 or 12 vials of 20 ml

Not all pack sizes may be marketed.