SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Romidys 1 mg/ml solution for injection.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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.
Clear almost colorless solution

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and cats.

4.2 Indications for use, specifying the target species

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.

4.3 Contraindications

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

4.4 Special warnings for each target species

As a dose-dependent increase in blood urea may occur in cats, sufficient fluid intake should be ensured.

4.5 Special precautions for use

i. 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).

ii. Special precautions to be taken by the person administering the medicinal products 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.

4.6 Adverse reactions (frequency and seriousness)

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.

4.7 Use during pregnancy, lactation or lay

The product should not be used in pregnant animals

4.8 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.

4.9 Amount(s) to be administered and administration route

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.
Sedation will be optimised if animals are allowed to stay in calm and quiet surroundings with minimal environment stimuli. In order to benefit from enhanced analgesia, it is recommended to allow sufficient time (usually 15 minutes) before initiating the procedure.

Sedation

Dogs:
0.04 - 0.12 ml Romidys 1mg/ml Solution for Injection per kg body weight provides a dose-related response (40 µg - 120 µg romifidine HCl/kg body weight).

When administered by i.v. injection, 80 µg romifidine HCl/kg bodyweight led to onset of sedation within approximately 5 minutes, the effect lasting 60 - 120 minutes.
When administered by s.c. injection (or i.m.), the onset of sedation is delayed, with depth of sedation lower than by the i.v. route until approximately 30 minutes after injection. The duration of sedation may be more prolonged.
In dogs, atipamezole solution, given by intramuscular injection 30 minutes after the intravenous administration of Romidys, will hasten recovery from the sedative effects of Romidys. A dose of 0.12 ml Romidys per kg bodyweight in dogs can be reversed with 200 µg atipamezole/kg.

Cats:
0.2 - 0.4 ml Romidys 1 mg/ml Solution for Injection per kg body weight provides a dose-related response (200 - 400 µg romifidine HCl/kg body weight).
When administered by i.m. injection, 200 µg/kg romifidine HCl/kg bodyweight led to onset of sedation within approximately 10 minutes, the effect lasting approximately 60 minutes. Although the duration of action is similar, a more rapid onset of sedation is achieved via the intravenous route of administration (within approximately 5 minutes).
In cats, atipamezole solution, given by intramuscular injection 30 minutes after the intramuscular administration of Romidys, will hasten the recovery from the sedative effects of Romidys. A dose of 0.4 ml Romidys per kg bodyweight in cats can be reversed with 400 µg atipamezole/kg.

Premedication

In clinical trials, premedication with romifidine has been followed by anaesthesia with propofol or thiopentone (and maintenance with halothane) in dogs, and by ketamine in cats. It should be noted that anaesthetic agents should be given to effect, depending on the individual response and the degree of surgical manipulation.

Dogs:
0.04 - 0.12 ml Romidys 1 mg/ml Solution for Injection per kg body weight provides a dose-related response (40 µg - 120 µg romifidine HCl/kg body weight).
Anaesthesia should be induced approximately 10 minutes after intravenous and 10-15 minutes after subcutaneous and intramuscular administration of Romidys 1 mg/ml solution for injection.

Cats:
0.2 ml Romidys 1 mg/ml Solution for Injection per kg bodyweight by i.m. injection, 10-15 minutes prior to i.m. injection of ketamine (10 mg/kg bodyweight) provides surgical anaesthesia for up to 30 minutes.
Increasing the dose of Romidys to 0.4 ml per kg bodyweight prior to ketamine, will extend the period of surgical anaesthesia.
In cats, it was shown that a " top-up dose " of 50% of the initial doses of romifidine and ketamine could be used to prolong anaesthesia.

4.10 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).

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC vet code: QN05CM93

Romifidine is an a α_2 -agonist of the imino-imidazolidine class.

Romifidine exerts sedative and analgesic effects. Its sedative effect is induced by stimulation of α_2 -receptors in the central nervous system. The substance possesses a strong specific affinity for these receptors.

5.2 Pharmacokinetic particulars

The mean absolute bioavailability of the injectable solution following intramuscular administration is 86% in dogs and 95% in cats. It is 92% following subcutaneous administration in dogs.
Maximal plasma concentrations after subcutaneous and intramuscular administration are obtained within approximately 50 minutes in dogs and approximately 25 minutes following intramuscular injection in cats, respectively.

Romifidine is rapidly distributed in the body with a volume of distribution of approximately 3 l/kg body weight for dogs and 6 l/kg body weight for cats, respectively following intravenous administration.

Romifidine is metabolised in the liver. The mean plasma elimination half-life is approximately 2 hours in dogs and 6 hours in cats. Approximately 80% of the administered dose is eliminated via urine and the remainder via faeces in dogs.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl hydroxybenzoate (E218)
Propyl hydroxybenzoate (E216)
Sodium chloride
Water for injection

6.2 Incompatibilities

None known.

6.3 Shelf-life

Unopened vial: 3 years
Broached vial: 28 days

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Colourless glass injection vial of 20 ml, closed with a rubber stopper and sealed with an aluminium cap.
- Box containing 1 or 12 vials of 20 ml

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

Any unused product or waste material should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

VIRBAC S.A.
1ère avenue - 2065 m - L.I.D.
06516 CARROS
FRANCE

8. MARKETING AUTHORISATION NUMBER

Vm 05653/4126

9. DATE OF FIRST AUTHORISATION

Date: 10 February 1999

10. DATE OF REVISION OF THE TEXT

Date: February 2011

Prohibition of sale, supply and/or use:

Veterinary medicinal product subject to prescription.