LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Cardboard box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Emedog, 1 mg/ml, solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml of solution contains:

Apomorphine ..... 1.0 mg

(equivalent to 1.17 mg of apomorphine hydrochloride hemihydrate)

3. PACKAGE SIZE

5 x 1 ml

20 x 1 ml

4. TARGET SPECIES

Dog

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous route only

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store in the original package. Protect from light.

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

DOMES PHARMA

3 RUE ANDRE CITROEN

63430 PONT-DU-CHATEAU

FRANCE

14. MARKETING AUTHORISATION NUMBERS

Vm 54982/3002

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{glass ampoule}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Emedog

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

1 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

EXP {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Emedog, 1 mg/ml, solution for injection for dogs

2. Composition

Each ml of solution contains:

Apomorphine ..... 1.0 mg

(equivalent to 1.17 mg of apomorphine hydrochloride hemihydrate)

Sodium metabisulfite (E223)..... 1.0 mg

Solution for injection.

Colourless or slightly yellow, clear liquid.

3. Target species

Dog

4. Indications for use

Induction of emesis.

5. Contraindications

Do not use in cases of depression of the Central Nervous System (CNS).

Do not use in cats and other species.

Do not use in cases of ingestion of caustic agents (acids or alkalies), foamy products, volatile substances, organic solvents and non-blunt objects (e.g. glass).

Do not use in animals which are hypoxic, dyspneic, seizuring, in hyperexcitation, extremely weak, ataxic, comatose, lacking normal pharyngeal reflexes, or suffering other marked neurologic impairments that could lead to aspiration pneumonia.

Do not use in cases of circulatory failure, shock and anesthesia.

Do not use in animals which are previously treated with Dopamine-Antagonists (Neuroleptics).

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special warnings:

Expulsive efforts with or without vomiting are likely to be seen from 2 and 15 minutes after the injection of the veterinary medicinal product and may last from to 2 minutes to 2.5 hours (as observed in one clinical trial).

Some dogs may not respond to this veterinary medicinal product. If emesis is not induced following a single injection, do not repeat the injection, as it will not be effective and may provoke clinical signs of toxicity (see section “Overdose”).

Special precautions for safe use in the target species:

In dogs with known severe hepatic failure, the risk/benefit balance should be considered by the veterinarian.

Before administering the veterinary medicinal product, consideration must be given to the time of the ingestion of the substance (in relation to gastric emptying times) and on the suitability of inducing emesis based on the type of substance ingested (see section 5. Contraindications also).

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

This veterinary medicinal product may cause nausea and somnolence. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician. DO NOT DRIVE, as sedation may occur.

Apomorphine has been shown to have teratogenic effects in laboratory animals and is excreted in breast milk. Pregnant or breast-feeding women should avoid handling the veterinary medicinal product.

This veterinary medicinal product may cause hypersensitivity reactions. People with known hypersensitivity to apomorphine or any of the excipients should avoid contact with the veterinary medicinal product.

If the veterinary medicinal product comes into contact with the skin or eyes, rinse immediately with water.

Wash hands after use.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation in dogs.

Apomorphine has been shown to have teratogenic effects in rabbits and foetotoxic effects in rats at doses higher than the recommended dose in dogs.

As apomorphine is excreted in breast milk, when used in lactating females, puppies should be monitored carefully for undesired effects.

Use only in accordance with the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

Neuroleptics (e.g.: chlorpromazine, haloperidol), and anti-emetics (metoclopramide, domperidone) reduce or suppress the emesis induced by the administration of apomorphine.

The administration or the prior ingestion of opiates or barbiturates can induce additive CNS effects and respiratory depression with apomorphine.

Caution is advised when dogs are receiving other dopamine agonist like cabergoline due to possible additive effects such as exacerbation or inhibition of vomiting.

Overdose:

Excessive doses of apomorphine may result in respiratory and/or cardiac depression, CNS stimulation (excitement, seizures) or depression, protracted vomiting, or rarely in restlessness, excitement or even convulsion.

Naloxone may be used to reverse the CNS and respiratory effects of apomorphine (but not cardiac side effects).

Maropitant (or dopamine receptor antagonists such as metoclopramide) should be considered in cases of protracted vomiting.

Major incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

In dogs:

Very common (>1 animal / 10 animals treated):
Drowsiness[1],
Decreased (or loss) appetite[1], increased salivation[1],
Immediate pain upon injection (mild to moderate)[1]
Common (1 to 10 animals / 100 animals treated):
Dehydration (slight)[1],
Cardiac rhythm disorders[1,2]
Very rare (<1 animal / 10,000 animals treated, including isolated reports): Ataxia

[1] These adverse events are transient and may be related to the physiological response to expulsive efforts.

[2] Tachycardia followed by bradycardia.

Multiple episodes of vomiting may be observed, and vomiting may occur up to several hours after the injection.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to either the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system : <{national system details}.>

8. Dosage for each species, routes and method of administration

Subcutaneous route only.

Single injection at a dosage of 0.1 mg of apomorphine/kg bodyweight (equivalent to 1 ampoule of 1 ml/10 kg BW).

To ensure a correct dosage, body weight should be determined as accurately as possible.

9. Advice on correct administration

None.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Store in the original package. Protect from light.

Any solution remaining in the ampoule following withdrawal of the required dose should be discarded.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the container: use immediately after opening.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Marketing authorisation numbers:

Vm 54982/3002

Pack sizes:

5 x 1 ml

20 x 1 ml

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

08/2022

Detailed information on this veterinary medicinal product is available in the Union Product Database.

(https://medicines.health.europa.eu/veterinary)

16. Contact details

Marketing authorisation holder <and contact details to report suspected adverse reactions>:

DOMES PHARMA

3 RUE ANDRE CITROEN

63430 PONT-DU-CHATEAU

FRANCE

Manufacturer responsible for batch release:

HAUPT PHARMA LIVRON

Rue du Comte de Sinard

26250 LIVRON SUR DRÔME

FRANCE

<Local representatives <and contact details to report suspected adverse reactions>:

17. Other information

At low doses, apomorphine induces emesis by stimulation of the dopamine receptors in the chemoreceptor trigger zone (CTZ). Higher doses of apomorphine, however, may suppress vomiting by stimulating the μ receptors in the vomiting centre in the brain.

Approved 26 May 2023