1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Emedog 1 mg/ml solution for injection for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of solution contains:

Active substance:
Apomorphine ..... 1.0 mg
(equivalent to 1.17 mg of apomorphine hydrochloride hemihydrate)

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Sodium metabisulfite (E223)	1.0 mg
Hydrochloric acid, concentrated (for pH adjustment)	
Water for injections	

Solution for injection.
Colourless or slightly yellow, clear liquid.

3. CLINICAL INFORMATION

3.1 Target species

Dog.

3.2 Indications for use for each target species

Induction of emesis.

3.3 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.

3.4 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 3.10 “Symptoms of overdose (and where applicable, emergency procedures and antidotes)”.

3.5 Special precautions for use

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 the type of substance ingested (see also section 3.3).

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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See section "contact details" of the package leaflet.

3.7 Use during pregnancy, lactation or lay

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

Pregnancy and lactation

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.

3.8 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.

3.9 Administration routes and dosage

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

For administration by a veterinarian or under their direct supervision

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QN04BC07

4.2 Pharmacodynamics

Apomorphine is an aporphine derivative of the dibenzoquinoline class and a synthetic derivative of morphine with no analgesic, opiate or addictive properties. 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.

4.3 Pharmacokinetics

Absorption
After subcutaneous administration apomorphine is rapidly absorbed. Peak plasma concentration (Cmax) is of 28.10 ± 7.58 ng/ml and is reached after about 20 minutes.

Distribution
Apomorphine is very lipophilic and equilibrates rapidly between blood and tissue. Apomorphine binds extensively to plasma proteins.

Metabolism
Apomorphine is conjugated in the liver (glucuronidation and methylation) into non-active metabolites.

Excretion
Apomorphine is excreted in urine, mostly as the metabolites with some unchanged (<2%). It is also excreted in breast milk. The half-life of the veterinary medicinal product is 25.9 ± 4.4 minutes.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 4 years.
Shelf life after first opening the immediate packaging: use immediately after opening.

5.3 Special precautions for storage

Store in the original package. Protect from light.
Any solution remaining in the ampoule following withdrawal of the required dose should be discarded.

5.4 Nature and composition of immediate packaging

Cardboard box of 5 colourless glass ampoules type I of 1 ml.
Cardboard box of 20 colourless glass ampoules type I of 1 ml.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

DOMES PHARMA

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database. (https://medicines.health.europa.eu/veterinary)