

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml of solution contains:

Active substance:

Apomorphine 1.0 mg
(corresponding to 1.17 mg of apomorphine hydrochloride hemihydrate)

Excipients:

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

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

Induction of emesis.

4.3 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, seizing, 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.

4.4 Special warnings for each target species

Expulsive efforts with or without vomiting are likely to be seen from 2 and 15 minutes after the injection of the product and may last from 2 minutes to 2,5 hours (as observed in one clinical trial).

Some dogs may not respond to this 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 (symptoms, emergency procedures, antidotes), if necessary").

4.5 Special precautions for use

Special precautions for use in animals:

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

Before administering the 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 section 4.3 also).

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

This 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 product.

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

If the product comes into contact with the skin or eyes, rinse immediately with water. Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Minor adverse reactions may be observed:

- drowsiness (very common),
- modification of appetite (very common),
- increased salivation (very common),
- mild to moderate pain on injection (very common),
- slight dehydration (common).
- change in cardiac frequency (tachycardia followed by bradycardia) (common).

They are transient and may be related to the physiological response to expulsive efforts.

In addition, based on the post marketing experience, ataxia has been reported very rarely.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions)

- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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

4.7 Use during pregnancy, lactation or lay

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

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

4.8 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.

4.9 Amounts to be administered and administration route

For subcutaneous administration only.

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

Animal weight should be accurately determined to ensure the administration of the correct dose.

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

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.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Dopamine agonists.
ATC vet code: QN04BC07.

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

Absorption

After subcutaneous administration apomorphine is rapidly absorbed. Peak plasma concentration (C_{max}) 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 product is 25.9 ± 4.4 minutes.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium metabisulfite (E223)
Hydrochloric acid, concentrated (for pH adjustment)
Water for injections

6.2 Major incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: Use immediately after opening.

6.4 Special precautions for storage

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

6.5 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.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Domes Pharma SC
57 rue des Bardines
63370 Lempdes
France

8. MARKETING AUTHORISATION NUMBER

Vm 35079/4003

9. DATE OF FIRST AUTHORISATION

14 July 2015

10. DATE OF REVISION OF THE TEXT

March 2021

Approved 17 March 2021

