# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Apovomin 1 mg/ml solution for injection for dogs

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:

**Active substance:**

| | |
|---|---|
| Apomorphine hydrochloride hemihydrate | 1.00 mg |
| (equivalent to apomorphine | 0.85 mg) |

**Excipients:**

| | |
|---|---|
| Benzyl alcohol (E1519) | 10.0 mg |
| Sodium metabisulfite (E223) | 1.0 mg |

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Solution for injection.
Clear, colourless aqueous solution.

## 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 case of depression of the Central Nervous System (CNS).
Do not use in cases of ingestion of caustic agents (acids or alkalis), foamy products, volatile substances, organic solvents and non-blunt objects (e.g. glass).
Do not use in animals which are hypoxic, dyspnoeic, 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 anaesthesia.
Do not use in animals which have been treated with Dopamine-Antagonists (Neuroleptics) in the past 24 hours.
Do not use in known 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 3 to 4 minutes after the injection of the product and may last up to half an hour.

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 overdose.

## 4.5 Special precautions for use

Special precautions for use in animals
In dogs with known severe hepatic failure, the benefit/risk balance for use of the product in such animals 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 the suitability of inducing emesis based on the type of substance ingested (see also section 4.3).

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 and breastfeeding women should avoid handling the product.
This product may cause hypersensitivity reactions. People with known hypersensitivity to apomorphine or to 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 during 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. Multiple episodes of vomiting may be observed, and vomiting may occur up to several hours after the injection. Apomorphine may lower blood pressure.

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

## 4.7 Use during 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.
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 according to the benefit/risk assessment by the responsible veterinarian.

### 4.8 Interaction with other medicinal products and other forms of interactions

Neuroleptics with a dopaminergic antagonistic effect (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 agonists, such as cabergoline, due to possible additive effects such as exacerbation or inhibition of vomiting.

### 4.9 Amounts to be administered and administration route

For single subcutaneous use only.
0.1 mg of apomorphine hydrochloride hemihydrate per kg bodyweight (0.1 ml product per kg bodyweight).
Animals should be accurately weighed to ensure administration of the correct dose.
Do not use if the solution has turned green.

### 4.10 Overdose (symptoms, emergency procedures, antidotes)

Excessive doses of apomorphine may result in respiratory and/or cardiac depression, CNS stimulation (excitement, seizures, stereotypy) or depression, protracted vomiting, slight decrease in body temperature or rarely in restlessness, excitement or even convulsion.
At higher doses apomorphine may also suppress vomiting.
Naloxone may be used to reverse the CNS and respiratory effects of apomorphine.
Anti-emetics such as metoclopramide and maropitant should be considered in case of protracted vomiting.

### 4.11 Withdrawal periods

Not applicable.

## 5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Dopamine agonists
ATCvet 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 D2-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 35.5 ± 7.46 ng/ml and is reached after about 13.5 ± 5.3 minutes.
Distribution
Apomorphine is very lipophilic and equilibrates rapidly between blood and tissue. Apomorphine binds extensively to plasma proteins in humans.
Metabolism
Apomorphine is extensively metabolised by the liver into-non-active metabolites.
Excretion
The metabolites and very little unchanged apomorphine (<2%) are excreted via the urine.

# 6. PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Benzyl alcohol (E 1519)
Sodium metabisulfite (E 223)
Sodium chloride
Water for injections
Sodium hydroxide (for pH adjustment)
Hydrochloric acid, diluted (for pH adjustment)

## 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 opening of the immediate packaging: 28 days.

## 6.4 Special precautions for storage

Store in the original package in order to protect from light.
Store in a refrigerator (2°C to 8°C).

## 6.5 Nature and composition of the immediate packaging

Clear Type I glass vials containing 5 ml, closed with a coated Type I bromobutyl rubber stopper and sealed with an aluminium cap. Each vial is packed into a cardboard box.

## 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

Dechra Regulatory B.V.
Handelsweg 25
Bladel
5531 AE
The Netherlands

## 8. MARKETING AUTHORISATION NUMBER

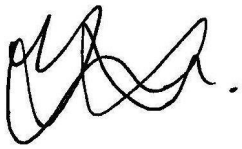
Vm 50406/4012

## 9. DATE OF FIRST AUTHORISATION

15 December 2020

## 10. DATE OF REVISION OF THE TEXT

December 2020



Approved: 15 December 2020