SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Apovomin 3 mg/ml solution for injection for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Apomorphine	2.56 mg
(equivalent to apomorphine hydrochloride hemihydrate	3.00 mg)

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl alcohol (E1519)	10 mg
Sodium metabisulfite (E223)	1.0 mg
Sodium chloride	
Water for injections	
Sodium hydroxide (for pH adjustment)	
Hydrochloric acid, diluted (for pH adjustment)	

Clear, colourless aqueous solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

Induction of emesis.

3.3 Contraindications

Do not use in cats.
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 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 to 15 minutes after the injection of the veterinary medicinal product and may last from 2 minutes to 2.5 hours. 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

In dogs with known severe hepatic failure, the benefit-risk balance for use of the veterinary medicinal product in such animals 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 medical 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[a]; Decreased appetite[a]; Hypersalivation[a]; Immediate pain upon injection[a, b].
Common (1 to 10 animals / 100 animals treated):	Dehydration[a, c]; Tachycardia[a], Bradycardia[a].
Undetermined frequency (cannot be estimated from the available data)	Low blood pressure.

[a] Transient and may be related to the physiological response to expulsive efforts.
[b] Mild to moderate.
[c] Slight.

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 the package leaflet for respective contact details.

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 according to 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 agonists, such as cabergoline, due to possible additive effects such as exacerbation or inhibition of vomiting.

3.9 Administration routes and dosage

Subcutanoeus use.

For single subcutaneous administration only.
0.05-0.1 mg of apomorphine hydrochloride hemihydrate per kg bodyweight (approximately 0.02-0.03 ml veterinary medicinal product per kg bodyweight).
An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes. To ensure a correct dosage, body weight should be determined as accurately as possible.
Do not use if the solution has turned green.

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.
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.

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

Not applicable.

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 lower doses apomorphine induces emesis by stimulation of the dopamine D2-receptors in the chemoreceptor trigger zone (CTZ).

Higher doses of apomorphine may suppress vomiting by stimulation of the μ receptors in the vomiting centre of the brain.

4.3 Pharmacokinetics

After subcutaneous administration apomorphine is rapidly absorbed.
Apomorphine binds extensively to plasma proteins.
Apomorphine is extensively metabolised by the liver into non-active metabolites. The metabolites and very little unchanged apomorphine (<2%) are excreted via the urine. It is also excreted in breast milk.

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: 36 months.
Shelf life after first opening of the immediate packaging: 28 days.

5.3 Special precautions for storage

5 ml and 10 ml vial: Store in a refrigerator (2°C to 8°C). Do not freeze.
20 ml vial: Do not freeze.

5.4 Nature and composition of immediate packaging

Clear Type I glass vials containing 5, 10 or 20 ml, closed with a coated bromobutyl rubber stopper and sealed with an aluminium cap. Each vial is packed into a cardboard box.

Pack sizes:
Box with 1 vial of 5 ml
Box with 1 vial of 10 ml
Box with 1 vial of 20 ml

Multi-pack with 10 vials of 5 ml
Multi-pack with 10 vials of 10 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.

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

Dechra Regulatory B.V.

7. MARKETING AUTHORISATION NUMBER

Vm 50406/4002

8. DATE OF FIRST AUTHORISATION

14 February 2019

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

June 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall

Approved: 09 September 2025