

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Outer carton

Single pack: 5, 10 and 20 ml vials

Multi-pack: 10 x 5 ml and 10 x 10 ml vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Apovomin 3 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

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

3. PACKAGE SIZE

5 ml
10 ml
20 ml
10 x 5 ml
10 x 10 ml

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 28 days.
Once broached, use by . . .

9. SPECIAL STORAGE PRECAUTIONS

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

For the 20 ml vial:
Do not freeze.

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

Dechra Regulatory B.V.

14. MARKETING AUTHORISATION NUMBER

Vm 50406/4002

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS 5 ml / 10 ml / 20 ml glass vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Apovomin

5 ml

10 ml

20 ml

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Apomorphine hydrochloride hemihydrate 3 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.

Once broached, use by . . .

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Apovomin 3 mg/ml solution for injection for dogs

2. Composition

Each ml contains:

Active substance:

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

Excipients:

Benzyl alcohol (E1519)	10 mg
Sodium metabisulfite (E223)	1.0 mg

Clear, colourless aqueous solution.

3. Target species

Dogs.

4. Indications for use

Induction of emesis.

5. 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, 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 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.

6. Special warnings

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.

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 the section “*Contraindications*”).

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.

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 according to 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 agonists, such as 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.

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

<Special restrictions for use and special conditions for use:>

Major incompatibilities:

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

7. Adverse events

Dogs:

Very common (>1 animal / 10 animals treated):	Drowsiness ^a ; Decreased appetite ^a ; Hypersalivation ^a (increased salivation); Immediate pain upon injection ^{a, b} .
Common (1 to 10 animals / 100 animals treated):	Dehydration ^{a, c} ; Tachycardia ^a (rapid heart rate), Bradycardia ^a (slow heart rate).
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 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 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 at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

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

Subcutaneous 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).

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

9. Advice on correct administration

An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes. Do not use if the solution has turned green.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

For the 5 and 10 ml vial:

Store in a refrigerator (2°C to 8°C).

Do not freeze.

For the 20 ml vial:

Do not freeze.

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

Shelf life after first opening the immediate packaging : 28 days

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 50406/4002

Pack sizes:

Box with 1 vial of 5 ml, 10 ml or 20 ml.

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

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. Contact details

Marketing authorisation holder:

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

Manufacturer responsible for batch release:

Produlab Pharma B.V.
Forellenweg 16
4941 SJ Raamsdonksveer
The Netherlands

Local representatives and contact details to report suspected adverse reactions:

Dechra Veterinary Products Limited
Sansaw Business Park
Hadnall
Shrewsbury
Shropshire
SY4 4AS
United Kingdom
Tel: +44 (0) 1939 211200

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

POM-V

Gavin Hall

Approved: 09 September 2025