ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Outer carton
5 ml vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Apovomin 1 mg/ml solution for injection for dogs

apomorphine hydrochloride hemihydrate

2. STATEMENT OF ACTIVE SUBSTANCES

apomorphine hydrochloride hemihydrate 1 mg/ml
(equivalent to apomorphine 0.85 mg/ml)

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

5 ml

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
In-use shelf-life: 28 days.
Once broached use by…

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 50406/4012

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

5 ml glass vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Apovomin 1 mg/ml solution for injection

apomorphine hydrochloride hemihydrate

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

1 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

5 ml

4. ROUTE(S) OF ADMINISTRATION

SC

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Once broached use by….

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Apovomin 1 mg/ml solution for injection for dogs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Apovomin 1 mg/ml solution for injection for dogs

apomorphine hydrochloride hemihydrate

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

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

Clear, colourless aqueous solution.

4. INDICATION(S)

Induction of emesis.

5. 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.

6. ADVERSE REACTIONS

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).

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 inform your veterinary surgeon. Alternatively, you can report via your national reporting system.

7. TARGET SPECIES

Dogs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

9. ADVICE ON CORRECT ADMINISTRATION

Do not use if the solution has turned green.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
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 container: 28 days.
Store in the original package in order to protect from light.
Store in a refrigerator (2°C to 8°C).

12. SPECIAL WARNING(S)

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.

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 the section on adverse reactions).

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.

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.

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.

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.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

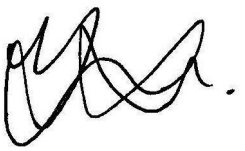
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Xxxxxx

15. OTHER INFORMATION

Clear Type I glass vials containing 5 ml, closed with a coated Type 1 bromobutyl rubber stopper and sealed with an aluminium cap. Each vial is packed into a cardboard box.



Approved: 15 December 2020