SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pardale-V 400 mg / 9 mg Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substances:

Paracetamol	400.0 mg
Codeine phosphate hemihydrate	9.0 mg

Excipients:

Qualitative composition of excipients and other constituents
Pregelatinised starch
Povidone (30K)
Maize starch
Magnesium stearate

White, flat tablets with a bevelled edge and a break-line.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

For analgesic therapy in dogs only. The veterinary medicinal product is indicated for acute pain of traumatic origin, as a complementary treatment in pain associated with other conditions, and post operative analgesia.

3.3 Contraindications

Do not exceed stated dose or duration of treatment.

Use is contraindicated in animals suffering from cardiac, hepatic or renal disease, where there is a possibility of gastrointestinal ulceration or bleeding, or where there is evidence of a blood dyscrasia or hypersensitivity to the product.

Do not use this product for cats.
Do not use in cases of hypersensitivity to the active substances or any of the excipients.

3.4 Special warnings

Seek veterinary advice if the treated condition does not improve or worsens during treatment, or if any side-effects or adverse reactions are experienced.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Use in animals less than 6 weeks of age or in aged animals may involve additional risk. If such use cannot be avoided, animals may require a reduced dosage and careful clinical management.

Avoid use in dehydrated, hypovolaemic or hypotensive animals, as there is a potential risk of increased renal toxicity.

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

This product may cause hypersensitivity (allergic) reactions in some people.
People with known hypersensitivity to codeine, paracetamol, or povidone should handle the product with care.
Allergic reaction to these substances may occasionally be serious. Do not handle this product if you know you are sensitive. If you develop symptoms following exposure, such as a skin rash, you should seek medical advice and show the physician this warning.
Accidental ingestion by children may lead to constipation, nausea, light-headedness, and/or sedation. Take care not to leave tablets within children's reach while preparing to administer the product. In case of accidental ingestion, particularly by a child, seek medical advice and show the physician this warning.
Return any unused whole or half tablets to the packaging provided and store out of the sight and reach of children.
Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Constipation[a], Vomiting[b], Diarrhoea[b] Lethargy, Anorexia

[a] Due to codeine content.

[b] Transient.

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

Pregnancy:
There are no known contraindications for use during pregnancy.

3.8 Interaction with other medicinal products and other forms of interaction

Concurrent administration of potentially nephrotoxic drugs should be avoided

3.9 Administration routes and dosage

For oral administration - 1 tablet/12 kg bodyweight every 8 hours.

Small dogs (up to 6 kg bodyweight):	½ tablet every 8 hours
Medium dogs (6 – 18 kg bodyweight):	½ - 1½ tablets every 8 hours
Large dogs (18 - 42 kg bodyweight):	1½ - 3½ tablets every 8 hours

Treat for a maximum of 5 days.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Immediately seek the advice of a veterinary surgeon and show him/her the product literature.

Carry out lavage and treat with intravenous injection of acetylcysteine (200 mg/ml) at a rate of 140 mg/kg every 6 hours for 7 treatments. Ascorbic acid (30 mg/kg) should also be given orally with each dose of acetylcysteine.

If necessary instigate fluid therapy using Ringers or bicarbonate solution.

Treat for codeine overdose with injection of Naloxone (1.0 mg/kg) repeated as necessary.

Provide oxygen support.

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:

QN02BE71

4.2 Pharmacodynamics

Paracetamol is a para aminophenyl derivative with analgesic properties.

Codeine is an opioid analgesic.

4.3 Pharmacokinetics

Both paracetamol and codeine are readily absorbed from the gastrointestinal tract. They are metabolised in the liver (codeine to morphine and narcodeine).

Codeine and its metabolites are excreted almost entirely by the kidney, whilst less than 5 % of paracetamol is excreted unchanged.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

5.3 Special precautions for storage

Do not store above 25 °C.

5.4 Nature and composition of immediate packaging

Polypropylene container with a low density polyethylene tamper evident lid, containing 100 or 500 plain white, flat tablets with bevelled edges and a break line on one side and DPL on the other.

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 50406/5027
Vm 50406/3022

8. DATE OF FIRST AUTHORISATION

15 April 1993

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

October 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.

Approved 09 December 2025
Gavin Hall