SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pardale-V Oral Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substances:

Paracetamol	400.0 mg
Codeine phosphate hemihydrate	9.0 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

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

4.3 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.

4.4 Special warnings for each target species

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

4.5 Special precautions for use

Special precautions for use in animals

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

Wash hands after use.

Other precautions

None.

4.6 Adverse reactions (frequency and seriousness)

Occasional constipation may occur due to codeine content.
During the post-marketing surveillance, transient gastrointestinal signs such as vomiting and diarrhoea and systemic signs such as lethargy and anorexia have been observed very rarely.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(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, lactation or lay

There are no known contraindications for use during pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction

Concurrent administration of potentially nephrotoxic drugs should be avoided.

4.9 Amounts to be administered and administration route

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal periods

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Analgesics, Other analgesics and antipyretics, Anilides
ATCVet Code: QN02BE71

5.1 Pharmacodynamic properties

Paracetamol is a para aminophenyl derivative with analgesic properties.

Codeine is an opioid analgesic.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Pregelatinised starch
Povidone (30K)
Maize starch
Magnesium stearate

6.2 Major incompatibilities

Not applicable.

6.3 Shelf life

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

6.4 Special precautions for storage

Do not store above 25°C.

6.5 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

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
5531 AE Bladel
The Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 50406/5027

9. DATE OF FIRST AUTHORISATION

15 April 1993

10. DATE OF REVISION OF THE TEXT

February 2025

Gavin Hall
Approved: 13 February 2025