PARTICULARS TO APPEAR ON THE OUTER PACKAGE - LABEL (part of concertina label/leaflet)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pardale-V 400 mg / 9 mg Tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:
Paracetamol 400 mg
Codeine phosphate hemihydrate 9 mg

3. PACKAGE SIZE

100 tablets
500 tablets

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.

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 NUMBERS

Vm 50406/5027
Vm 50406/3022

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Pardale-V 400 mg / 9 mg Tablets

2. Composition

Each tablet contains:

Active substances:
Paracetamol 400 mg
Codeine phosphate hemihydrate 9 mg

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

3. Target species

Dogs.

4. Indications for use

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.

5. Contraindications

Do not exceed the stated dose or the duration of treatment.
Use is contraindicated in animals suffering from cardiac, hepatic or renal disease, where there is the possibility of gastrointestinal ulceration or bleeding, or where there is evidence of blood dyscrasia or hypersensitivity to the product.
Do not use this preparation for cats.
Do not use in cases of hypersensitivity to the active substance or any of the excipients.

6. Special warnings

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

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.

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

Interaction with other medicinal products and other forms of interaction:
Concurrent administration of potentially nephrotoxic drugs should be avoided.

Overdose:
Immediately seek medical advice of a veterinary surgeon showing them 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 Ringer's or bicarbonate solution.
Treat for codeine overdose with injection of naloxone (1.0 mg/kg) repeated as necessary.
Provide oxygen support.

Major incompatibilities:
Not applicable.

7. 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 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

For oral use.
1 tablet per 12 kg body weight every 8 hours.
Small dogs (up to 6 kg body weight): ½ tablet every 8 hours.
Medium dogs (6-18 kg body weight): ½-1 ½ tablets every 8 hours.
Large dogs (18-42 kg body weight): 1 ½ -3 ½ tablets every 8 hours.
Treat for a maximum of 5 days.

9. Advice on correct administration

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25 °C.

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

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 50406/5027
Vm 50406/3022

Containers of 100 or 500 tablets.
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:
Dales Pharmaceuticals Limited
Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire
BD23 2RW
United Kingdom

Genera d.d.
Svetonedeljska cesta 2
Kalinovica
10436 Rakov Potok,
Croatia

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: 05 January 2026