MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pardale-V Oral Tablets

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each tablet contains: Active substances:
Paracetamol 400 mg; Codeine phosphate hemihydrate 9 mg

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

100 tablets
500 tablets

5. TARGET SPECIES

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Small dogs (up to 6 kg body weight): ½ tablet every 8 hours.
Medium dogs (6-18 kg body weight): ½-1½ tablets every 8 hours.
Large dogs (18-42 kg body weight): 1½-3½ tablets every 8 hours.
Treat for a maximum of 5 days.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Do not use this product in cats.

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

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

Dispose of empty packaging and any remaining product
in the household refuse.

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

For animal treatment only
To be supplied only on veterinary prescription.

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 Limited
Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire
BD23 2RW
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 10434/4034

17. MANUFACTURER'S BATCH NUMBER

Lot:

Package Leaflet:
Pardale-V Oral tablets

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 Limited
Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire
BD23 2RW
United Kingdom

Manufacturer responsible for batch release:
Dales Pharmaceuticals Limited
Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire
BD23 2RW
United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pardale-V Oral tablets

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

Each tablet contains:

Active substances:
Paracetamol 400 mg
Codeine phosphate hemihydrate 9 mg

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

4. INDICATION(S)

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.

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. ADVERSE REACTIONS

Occasional constipation 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).

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.

7. TARGET SPECIES

Dogs.

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

For oral administration.
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 PERIOD

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.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Seek medical advice if the treated condition does not improve or worsens during treatment.

Special precautions for use in animals:
Use in animals less than 6 weeks of age or in aged animals may involve additional risks.
If such use cannot be avoided, animals may require a reduced dose and careful clinical management.
Avoid use in dehydrated, hypovolaemic or hypotensive animals as there is a potential risk or increased renal toxicity.

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

Wash hands after use.

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

Interactions with other medicinal products and other forms of interaction:

Concurrent administration of potentially nephrotoxic drugs should be avoided.

Overdose (symptoms, emergency procedures, antidotes):
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.

Incompatibilities:
Not applicable.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS

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

14. DATE ON WHICH THE LABEL WAS LAST APPROVED

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

For animal treatment only.

POM-V Prescription Only Medicine - Veterinarian

16. MARKETING AUTHORISATION NUMBER

Vm 10434/4034

17. OTHER INFORMATION

Containers of 100 or 500 tablets.
Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.
Dechra Veterinary Products Limited, Sansaw Business Park, Hadnall, Shrewsbury, Shropshire, SY4 4AS, United Kingdom.

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Approved 13 December 2019