[Version 8, 10/2012]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF VETERINARY MEDICINAL PRODUCT

Pardale-V Oral Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active ingredients

Paracetamol	400.0 mg
Codeine phosphate hemihydrate	9.0 mg

For a 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.

Do not administer other NSAIDs concurrently or within 24 hours of each other.

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.

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.

NSAIDs can cause inhibition of phagocytosis and hence, in the treatment of inflammatory conditions associated with bacterial infections, appropriate concurrent antimicrobial therapy should be instigated.

4.5 Special precautions for use

i) 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.

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

Wash hands after use.

iii) Other precautions

None.

4.6 Adverse reactions (frequency and seriousness)

Occasional constipation may occur due to codeine content.

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

Some NSAIDs may be highly bound to plasma proteins and compete with other highly bound drugs to produce an increase in non-bound pharmacologically active concentrations, which can lead to toxic effects.

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 PARTICULARS

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

5.1 Pharmacodynamic properties

Paracetamol is a para aminophenyl derivative with analgesic properties.

Codeine is an opioid analgesic.

5.2 Pharmacokinetic properties

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 Incompatibilities

None known.

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 contents 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.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

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

8. MARKETING AUTHORISATION NUMBER

10434/4034

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15/04/1993
Date of renewal of the authorisation: 10/10/2007

10. DATE OF ANY REVISION OF THE TEXT

26 January 2016

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pardale-V oral tablets
For dogs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 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

Dogs

6. INDICATION(S)

For analgesic therapy in dogs only.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
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 - 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

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.Do not use this product in cats.

10. EXPIRY DATE

EXP: {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°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 Limited
Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire
BD23 2RW
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 10434/4034 NFA-VPS

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
Pardale-V
Oral tablets 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 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 for dogs

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

1 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

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.
Do not administer other NSAIDs concurrently or within 24 hours of each other.
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.

6. ADVERSE REACTIONS

Occasional constipation may occur due to codeine content.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

8. DOSAGE, ROUTE 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 - 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.

9. ADVICE ON CORRECT ADMINISTRATION

None

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 25^{o}C.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after 'EXP'.

12. SPECIAL WARNINGS

Special warnings for each target species:
Seek veterinary advice if the treated condition does not improve or worsens during treatment. NSAIDs can cause inhibition of phagocytosis and hence, in the treatment of inflammatory conditions associated with bacterial infections, appropriate concurrent antimicrobial therapy should be instigated.

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.

User warnings:
Wash hands after use.

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

Interaction with other medicinal products and other forms of interaction:
Some NSAIDs may be highly bound to plasma proteins and compete with other highly bound drugs to produce an increase in non-bound pharmacologically active concentrations, which can lead to toxic effects.
Concurrent administration of potentially nephrotoxic drugs should be avoided.

Overdose (symptoms, emergency procedures, antidotes):
Immediately seek the 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:
None known.

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

26 January 2016

15. OTHER INFORMATION

NFA-VPS

Non-Food Animal Medicine - Veterinarian, Pharmacist, Suitably Qualified Person

For animal treatment only.Containers of 100 or 500 tablets.
Not all pack sizes may be marketed.

Local representative:
Dechra Veterinary Products Limited, Sansaw Business Park, Hadnall, Shrewsbury, Shropshire, SY4 4AS, United Kingdom