

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprieve 50 mg Tablets for Dogs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:

Carprofen 50 mg

Excipients:

Qualitative composition of excipients and other constituents
Cellulose, Microcrystalline
Lactose Monohydrate
Croscarmellose Sodium
Povidone K30
Sodium Laurilsulfate
Magnesium Stearate

A white/off white circular tablet with a break line on one face and "50" scored on the opposing face.

3 CLINICAL INFORMATION

3.1 Target Species

Dogs.

3.2 Indications for use, for each target species

For analgesia and reduction of chronic inflammation in musculoskeletal disturbances in dogs, for example in degenerative joint disease.

3.3 Contraindications

Do not use in cats. Do not use in dogs 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. Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Use in dogs less than 6 weeks of age, or in aged animals, may involve additional risk. If such use cannot be avoided, such dogs may require a reduced dosage and careful clinical management. Avoid use in any dehydrated, hypovolaemic or hypotensive dog, as there is a potential risk of increased renal toxicity. NSAIDs can cause inhibition of phagocytosis and hence in the treatment of inflammatory conditions associated with bacterial infection, appropriate concurrent antimicrobial therapy should be instigated.

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

None.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse reactions

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Renal disorder ¹ Hepatopathy ¹ Vomiting ² , Diarrhoea ² , Blood in faeces ² , Appetite loss ² , Lethargy ²
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¹As with other NSAIDs there is a risk of renal or idiosyncratic hepatic adverse events.

²Typical undesirable effects associated with NSAIDs that generally occur within the first week of treatment. Transient and disappear after treatment is stopped, but in very rare cases, may be serious or fatal. If adverse reactions occur, stop treatment, and seek the advice of a veterinarian.

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 nation competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

The use is not recommended during pregnancy or lactation.

3.8 Interaction with other medicinal products and other forms of interactions

Do not administer NSAIDs concurrently or within 24 hours of each other. Some NSAIDs may be highly bound to plasma proteins and compete with other highly bound drugs, which can lead to toxic effects.

Concurrent administration of potential nephrotoxic drugs should be avoided. Gastrointestinal tract ulceration may be exacerbated by corticosteroids in animals given non-steroidal anti-inflammatory drugs.

Monitor drug compatibility closely where adjunctive therapy is required.

3.9 Administration routes and dosage

For oral use.

The tablets can be divided into equal halves.

An initial dose of 2 to 4 mg carprofen/kg bodyweight/day is recommended to be given as a single daily dose or in 2 equally divided doses. To ensure a correct dosage body weight should be determined as accurately as possible.

The dose may be reduced to 2 mg carprofen/kg bodyweight/day administered as a single daily maintenance dose after 7 days, subject to clinical response: see maintenance dose table below:

Maintenance Dose Table	Number of tablets per dose
Bodyweight (kg)	50 mg
5.0	-
10.0	-
12.5	1/2
15.0	-
20.0	-
25.0	1
37.5	1 + 1/2
50	2

Duration of treatment will be dependent upon the response seen. Long-term treatment should be under regular veterinary supervision.

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

Do not exceed the stated dose. There is no specific antidote for carprofen overdosage but general supportive therapy, as applied to clinical overdosage with NSAIDs should be applied.

3.11 Special restrictions for use and special conditions for use, indicating 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:

QM01AE91

4.2 Pharmacodynamics

Carprofen, (±)-6-chloro-α-methylcarbazole-2-acetic acid, is a non-steroidal anti-inflammatory drug

(NSAID). It is a derivative of phenylpropionic acid and a member of the arylpropionic acid class of NSAIDs. As a representative of the 2-arylpropionic family, it contains a chiral center at C₂ of the propionic moiety and therefore, exists in 2 stereoisomeric forms, the (+)-S and (-)-R enantiomers. Carprofen, like most other NSAIDs is an inhibitor of the enzyme cyclo-oxygenase of the arachidonic acid cascade. It has been reported that the inhibition of prostaglandin synthesis by Carprofen is slight in relation to its anti-inflammatory and analgesic potency. The precise mode of action of Carprofen is not clear.

4.3 Pharmacokinetics

Following oral administration of 4 mg carprofen/kg to dogs, peak plasma concentrations (mean C_{max} = 28.51 microgram/ml) were achieved in 4 hours.

Absorption of carprofen is rapid and complete in the dog. The volume of distribution is small with the highest drug concentrations occurring in plasma. Ratios of tissue to plasma concentration are less than one which is consistent with a high level of binding of carprofen to plasma proteins.

5 PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale:

Polypropylene tubs: 3 years.

Blister packs: 2 years.

5.3 Special precautions for storage

Do not store above 25°C.

Store in a dry place.

Protect from light.

5.4 Nature and composition of immediate packaging

Polypropylene snap secure tubs sealed with cotton wool and white polyethylene snap secure caps in tubs of 100 and 500. Alu/Alu blister strips containing 10 (50 mg) tablets per strip in cartons of 20, 100 and 500 tablets.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

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

Norbrook Laboratories (Ireland) Limited

7 MARKETING AUTHORISATION NUMBER(S)

8 DATE OF FIRST AUTHORISATION

25 July 2003

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

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (<https://medicines.health.europa.eu/veterinary>).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{CARTON}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CARPRIEVE 50 mg TABLETS FOR DOGS

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:

Carprofen 50 mg

3. PACKAGE SIZE

Blister strips containing 10 (50 mg) tablets per strip [in packs of 20 and 100 and 500].

4. TARGET SPECIES

Dogs.

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

For oral use.

An initial dose of 2 to 4 mg carprofen/kg bodyweight/day is recommended to be given as a single daily dose or in 2 equally divided doses. To ensure a correct dosage body weight should be determined as accurately as possible.

The dose may be reduced to 2 mg carprofen/kg bodyweight/day administered as a single daily maintenance dose after 7 days, subject to clinical response: see maintenance dose table below:

Maintenance Dose Table	Number of tablets per dose	
Bodyweight (kg)	20 mg	50 mg
5.0	●	-
10.0	●	-
12.5	-	●
15.0	●●	-
20.0	●●	-
25.0	-	●
37.5	-	●●
50	-	●●

Duration of treatment will be dependent upon the response seen. Long-term treatment should be under regular veterinary supervision.

7. WITHDRAWAL PERIOD

8. EXPIRY DATE

Exp: {mm/yyyy}

Do not use after the expiry date.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

Store in a dry place.

Protect from light.

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

Norbrook Laboratories (Ireland) Limited

14. MARKETING AUTHORISATION NUMBER(S)

15. BATCH NUMBER

Lot: {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{TUB/LABEL}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprieve 50 mg TABLETS FOR DOGS

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:

Carpofen 50 mg

3. TARGET SPECIES

Dogs.

4. ROUTES OF ADMINISTRATION

For oral use.

An initial dose of 2 to 4 mg carprofen/kg bodyweight/day is recommended to be given as a single daily dose or in 2 equally divided doses. To ensure a correct dosage body weight should be determined as accurately as possible.

The dose may be reduced to 2 mg carprofen/kg bodyweight/day administered as a single daily maintenance dose after 7 days, subject to clinical response: see maintenance dose table below:

Maintenance Dose Table	Number of tablets per dose	
Bodyweight (kg)	20 mg	50 mg
5.0	●	-
10.0	●	-
12.5	-	●
15.0	●●	-
20.0	●●	-
25.0	-	●●
37.5	-	●●●
50	-	●●●●

Duration of treatment will be dependent upon the response seen. Long-term treatment should be under regular veterinary supervision.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

Exp: {mm/yyyy}

Do not use after the expiry date.

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

Store in a dry place.

Protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER
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Norbrook Laboratories (Ireland) Limited

LOGO

9. BATCH NUMBER

Lot: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{BLISTER PACK/LABEL}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CARPRIEVE 50 mg TABLETS FOR DOGS

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each tablet contains:

Carprofen 50 mg

3. BATCH NUMBER

Lot: {number}

4. EXPIRY DATE

Exp: {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

CARPRIEVE 20 mg TABLETS FOR DOGS
CARPRIEVE 50 mg TABLETS FOR DOGS

2. Composition

Each respective tablet contains:

Active Substance:

Carprofen	20 mg
Carprofen	50 mg

Excipients:**Qualitative composition of excipients and other constituents**

Cellulose, Microcrystalline

Lactose Monohydrate

Croscarmellose Sodium

Povidone K30

Sodium Laurilsulfate

Magnesium Stearate

A white/off white circular tablet with a break line on one face and "50" scored on the opposing face.

3. Target species

Dogs.

4. Indications for use

For analgesia and reduction of chronic inflammation, for example in degenerative joint disease, in dogs.

5. Contraindications

Use of this product in cats is contra-indicated.

Do not use in dogs 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. Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

10 Special warningsSpecial precautions for safe use in the target species:

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

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

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

Pregnancy and lactation:

The veterinary medicinal product is not indicated for use in pregnant or lactating bitches.

Interactions with other medicinal products and other forms of interaction:

Do not administer NSAIDs concurrently or within 24 hours of each other. Some NSAIDs may be highly bound to plasma proteins and compete with other highly bound drugs, which can lead to toxic effects.

Concurrent administration of potential nephrotoxic drugs should be avoided. Gastrointestinal tract ulceration may be exacerbated by corticosteroids in animals given non-steroidal anti-inflammatory drugs.

Monitor drug compatibility closely where adjunctive therapy is required.

Overdose:

Do not exceed the stated dose. There is no specific antidote for carprofen overdosage but general supportive therapy, as applied to clinical overdosage with NSAIDs should be applied.

7. Adverse events

Target species: Dogs

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Renal disorder ¹ Hepatopathy ¹ Vomiting ² , Diarrhoea ² , Blood in faeces ² , Appetite loss ² , Lethargy ²
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¹As with other NSAIDs there is a risk of renal or idiosyncratic hepatic adverse events.

²Typical undesirable effects associated with NSAIDs that generally occur within the first week of treatment. Transient and disappear after treatment is stopped, but in very rare cases, may be serious or fatal. If adverse reactions occur, stop treatment, and seek the advice of a veterinarian.

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 using the contact details at the end of this leaflet, or via your national reporting system:

8. Dosage for each species, routes and method of administration

For oral use.

The tablets can be divided into equal halves.

An initial dose of 2 to 4 mg carprofen/kg bodyweight/day is recommended to be given as a single daily dose or in 2 equally divided doses.

The dose may be reduced to 2 mg carprofen/kg bodyweight/day administered as a single daily maintenance dose after 7 days, subject to clinical response: see maintenance dose table below:

Maintenance Dose Table	Number of tablets per dose	
Bodyweight (kg)	20 mg	50 mg
5.0	●	-
10.0	●●	-
12.5	-	●
15.0	●●	-
20.0	●●●	-
25.0	-	●●
37.5	-	●●●
50	-	●●●●

9. Advice on correct administration

Duration of treatment will be dependent upon the response seen. Long-term treatment should be under regular veterinary supervision.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children

Do not store above 25°C.

Store in a dry place.

Protect from light.

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

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

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
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Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

VPA 22664/071/001-002

Packaging quantities:

100 x 20 mg tablets per tub

Blister strips containing 10 (20 mg) tablets per strip [in packs of 20 and 100].

100 x 50 mg tablets per tub.

500 x 50 mg tablets per tub.

Blister strips containing 10 (50 mg) tablets per strip [in packs of 20 and 100 and 500].

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (<https://medicines.health.europa.eu/veterinary>).

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

Norbrook Laboratories (Ireland) Limited

Rossmore Industrial Estate

Monaghan

Ireland

Tel: +44 (0)28 3025 4435

E-mail: phvdept@norbrook.co.uk

Manufacturer responsible for batch release:

Norbrook Manufacturing Limited

Rossmore Industrial Estate

Monaghan

Ireland

Norbrook Laboratories Limited

Station Works
Newry
Co. Down, BT35 6JP

17. Other information
