**ANNEX I**

**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprieve 20 mg Tablets for Dogs

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

**Active substance:**

Carprofen 20 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 "20" 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

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.

### 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:

Not applicable.

Special precautions for the protection of the environment:

Not applicable.

**3.6 Adverse events**

| | |
|---|---|
| Very rare<br><1 animal / 10,000 animals treated, including isolated reports): | Renal disorder[1] Hepatopathy[1]<br>Vomiting[2], Diarrhoea[2], Blood in faeces[2], Appetite loss[2], Lethargy[2] |

[1]As with other NSAIDs, there is a risk of rare renal or idiosyncratic hepatic adverse events.
[2]Typical undesirable effects associated with NSAIDs that generally occur within the first week of treatment.

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 national competent authority via the national reporting system. See 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.
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 |
| 5.0 | 1/2 |
| 10.0 | 1 |
| 12.5 | - |
| 15.0 | 1 ½ |
| 20.0 | 2 |
| 25.0 | - |
| 37.5 | - |
| 50 | - |

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, including 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 period(s)

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 $C_2$ of the propionic moiety and therefore, exists in 2 sterioisomeric 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 Cmax = 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 25ºC. 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. Alu/Alu blister strips containing 10 (20 mg) tablets per strip in cartons of 20 and 100 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 of 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. These measures should help to protect the environment.

## 6 NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited

## 7 MARKETING AUTHORISATION NUMBER(S)

## 8 DATE OF FIRST AUTHORISATION

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 20 mg TABLETS FOR DOGS

## 2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:

| | |
|---|---|
| Carprofen | 20 mg |

## 3. PACKAGE SIZE

20 tablets
100 tablets

## 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.

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 PERIODS**

**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 and 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 20 mg TABLETS FOR DOGS

## 2. STATEMENT OF ACTIVE SUBSTANCES

Each table contains:

| | |
|---|---|
| Carprofen | 20 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.
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.
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}

## 7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Store in a dry place and protect from light.

## 8. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited

## 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 20 mg TABLETS FOR DOGS

## 2. QUALITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE

Each tablet contains:
Carprofen 20 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 "20" scored on the opposing face.
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 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.

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 or hypersensitivity to the product.

## 6. Special warnings

Special warnings:

None.

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.

Pregnancy and lactation:

The use is not recommended during pregnancy or lactation.

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 reactions

| | |
|---|---|
| Very rare<br><1 animal / 10,000 animals treated, including isolated reports): | Renal disorder[1] Hepatopathy[1]<br>Vomiting[2], Diarrhoea[2], Blood in faeces[2], Appetite loss[2], Lethargy[2] |

[1]As with other NSAIDs, there is a risk of rare renal or idiosyncratic hepatic adverse events.

[2]Typical 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 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 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:

## 8. Dosage for each species, routes and method 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.

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 of 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. 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

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

June 2019

Detailed information of 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, BT35 6JP
Co. Down,
Northern Ireland

## 17. Other information