1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprogesic 20 mg tablets for dogs. (IE)
Profenacarp 20 mg tablets for dogs. (IT)

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

Reduction of inflammation and pain caused by musculoskeletal disorders and degenerative joint disease. As a follow up to parenteral analgesia in the management of post operative pain.

3.3 Contraindications

Do not use in cats.
Do not use in pregnant or lactating bitches.
Do not use in puppies less than 4 months of age.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
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 animals suffering from haemorrhagic syndrome.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Use in aged dogs may involve additional risk. If such a 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:

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands after handling the veterinary medicinal product.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

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]

[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 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 national 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 safety of the veterinary medicinal product has not been established during pregnancy and lactation. Laboratory studies in rats and rabbits have shown evidence of fetotoxic effects of carprofen at doses close to the therapeutic dose. Do not use in pregnant or lactating bitches.

3.8 Interaction with other medicinal products and other forms of interaction

Do not administer NSAIDs and glucocorticoids 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.

3.9 Administration routes and dosage

Oral use.

4 mg carprofen per kg bodyweight per day.

An initial dose of 4 mg carprofen per kg bodyweight per day given as a single dose or in two equally divided doses.
The daily dose may be reduced, subject to clinical response.
Duration of treatment will be dependent upon the response seen. Long-term treatment should be under regular veterinary supervision.
To extend analgesic and anti-inflammatory cover post-operatively parenteral pre-operative treatment with an injectable Carprofen product may be followed with Carprofen Tablets at 4 mg/kg/day for up to 5 days.
Return any halved tablets to the blister pack and use within 48 hours.
See dosage table below:

Bodyweight (kg)	Number of tablets to be administered twice daily
5.0	◖
10.0	●
15.0	●◖
20.0	●●

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 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 centre at C2 of the propionic moiety and therefore, exists in 2 sterioisomeric forms, the (+)-S and (-)-R enantiomers.

Carprofen possesses anti-inflammatory, analgesic and anti-pyretic activity.

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

Absorption is rapid with > 90 % absorption after oral administration. The volume of distribution is small and carprofen is highly bound to plasma proteins. Biotransformation of carprofen occurs in the

liver to form the ester glucuronide and two 1-O-acyl-β-D-glucuronide diastereoisomers. These are secreted in the biliary tract and excreted in the faeces.
The C_{max} is 28.51 µg/ml and the AUC is 237.33 µg/ml.hour.

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 ºC.

Protect from light.
Store in a dry place.

5.4 Nature and composition of immediate packaging

The veterinary medicinal product is supplied in either:
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 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

Date of first authorisation: 08 December 2006.

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

{DD/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

Carprogesic 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. 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.
Keep the blister in the outer carton.
Protect from light.
Store in a dry place.

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 NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{LABEL/TUB}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprogesic 20 mg tablets for dogs

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablets contains:
Carprofen 20 mg

3. PACKAGE SIZE

100 tablets

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.
4 mg carprofen per kg bodyweight per day.
An initial dose of 4 mg carprofen per kg bodyweight per day given as a single dose or in two equally divided doses. The daily dose may be reduced, subject to clinical response.
Duration of treatment will be dependent upon the response seen. Long-term treatment should be under regular veterinary supervision.
Do not exceed the stated dose.
To extend analgesic and anti-inflammatory cover post-operatively parenteral pre-operative treatment with an injectable Carprofen product may be followed with Carprofen Tablets at 4 mg/kg/day for up to 5 days.
Return any halved tablets to the blister pack and use within 48 hours.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.

Protect from light.
Store in a dry place.

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 NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{BLISTER PACK}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprogesic 20 mg tablets for dogs

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

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

Carprogesic 20 mg tablets for dogs.
Carprogesic 50 mg tablets for dogs.

2. Composition

Each tablet contains:

Active substance:	
Carprofen	20 mg
Carprofen	50 mg

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

Reduction of inflammation and pain caused by musculoskeletal disorders and degenerative joint disease. As a follow up to parenteral analgesia in the management of post operative pain.

5. Contraindications

Do not use in cats.
Do not use in pregnant or lactating bitches.
Do not use in puppies less than 4 months of age.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
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 animals suffering from haemorrhagic syndrome.

6. Special warnings

Special precautions for safe use in the target species:
Use in aged dogs may involve additional risk. If such a 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:
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician. Wash hands after handling the veterinary medicinal product.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation.
Laboratory studies in rats and rabbits have shown evidence of fetotoxic effects of carprofen at doses close to the therapeutic dose.
Do not use in pregnant or lactating bitches.

Interaction with other medicinal products and other forms of interaction:
Do not administer other NSAIDs and glucocorticoids 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.

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**

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]

[1]As with other NSAIDs there is a risk of rare renal or idiosyncratic hepatic adverse events.
[2]Typical undesirable effects associated with NSAIDs 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: <{national system details}

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

Oral use.
4 mg carprofen per kg bodyweight per day.
An initial dose of 4 mg carprofen per kg bodyweight per day given as a single dose or in two equally divided doses. The daily dose may be reduced, subject to clinical response.
Duration of treatment will be dependent upon the response seen. Long-term treatment should be under regular veterinary supervision.
To extend analgesic and anti-inflammatory cover post-operatively parenteral pre-operative treatment with an injectable Carprofen product may be followed with Carprofen Tablets at 4 mg/kg/day for up to 5 days.
See dosage table below:

Bodyweight (kg)	Number of tablets to be administered twice daily	
	20 mg	50 mg
5.0	◖	-
10.0	●	-
12.5	-	◖
15.0	●◖	-
20.0	●●	-

25.0	-	●
37.5	-	●◖
50	-	●●

9. **Advice on correct administration**

Do not exceed the stated dose.
Return any halved tablets to the blister pack and use within 48 hours.

10. **Withdrawal periods**

Not applicable.

11. **Special storage precautions**

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the blister and carton or the tubs after Exp.

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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. **Marketing authorisation numbers and pack sizes**

Carprogesic 20 mg Tablets:
Carprogesic 50 mg Tablets:

This veterinary medicinal product is supplied in either:
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
E-mail: phvdept@norbrook.co.uk
Tel: +44 (0)28 3026 4435

Manufacturer responsible for batch release:
Norbrook Laboratories Limited
Station Works
Camlough Road
NEWRY
Co. Down, BT35 6JP
Northern Ireland

Norbrook Manufacturing Ltd
Rossmore Industrial Estate
Monaghan
Ireland

17. Other information