1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprieve 100 mg tablets for Dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substances:

Carprofen 100 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Tartrazine (E102)	1.2 mg
Microcrystalline cellulose	
Lactose monohydrate	
Croscarmellose sodium	
Povidone K 30	
Sodium laurilsulphate	
Magnesium stearate	

A yellow circular tablet of 8 mm diameter embossed “100” on one side and a single break-line on the other side. The tablets can be divided into halves.

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.

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.
NSAIDs can cause inhibition of phagocytosis and hence in the treatment of inflammatory condition associated with bacterial infection, appropriate concurrent antimicrobial therapy should be instigated.
Avoid use in any dehydrated, hypoproteinemic, hypovolaemic or hypotensive dog, as there is a potential risk of increased renal toxicity.

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

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]

[1]As with other NSAIDs, there is a risk of 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 the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Studies in laboratory species (rats and rabbits) have shown evidence of foetotoxic effects of carprofen at doses close to the therapeutic dose. The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Do not use in pregnant or lactating bitches.

3.8 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.

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.
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 the veterinary medicinal product at 4 mg/kg/day for up to 5 days.
Return any halved tablets to the original pack and use at the next administration.
Any halved tablets remaining after the last administration of the veterinary medicinal product must be discarded.

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-chloror-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 stereoisomeric forms, the (+)-S and (-)-R enantiomer.

Carprofen possess 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. However 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: 2 years.

5.3 Special precautions for storage

Do not store above 25 °C.
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 containing 14, 30 or 100 tablets, sealed with a white low density Polyethylene Snap Secure Cap, or
Aluminium-Aluminium blister strips of 10 tablets in cartons containing 10, 20, 30, 50, 60, 70, 100, 140, 180, 200, 250, 280, 300, 500 or 1000 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.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland)

7. MARKETING AUTHORISATION NUMBER(S)

VPA22664/071/003

8. DATE OF FIRST AUTHORISATION

08/01/2010

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

09/04/2026

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).