1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eurofen 100 mg tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substances:

Carprofen 100.0 mg

Excipients:

Qualitative composition of excipients and other constituents
Lactose monohydrate
Microcrystalline cellulose
Silica colloidal anhydrous
Magnesium stearate

A plain round flat bevelled edge white to off white tablet with a breakline on one side.
The tablets can be divided into equal 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 musculo-skeletal 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 pups 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 gastro-intestinal 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, dogs may require careful clinical management.

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

Concurrent administration of potential nephrotoxic drugs should be avoided.

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 of the tablets, seek medical advice 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:

Rare (1 to 10 animals / 10 000 animals treated):	Renal disorder Hepatic disorder[1]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Vomiting[2], diarrhea[2], blood in faeces[2,3], loss of appetite[2], lethargy[2]

[1]Idiosyncratic reaction.
[2]Transient. Generally occur within the first treatment week and disappear following termination of the treatment. In very rare cases may be serious or fatal.
[3] Occult.

If adverse events occur, use of the veterinary medicinal product should be stopped and the advice of a veterinarian should be sought.

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

Carprofen must not be administered with glucocorticoids.

Do not administer other 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.

3.9 Administration routes and dosage

Oral use.
2 to 4 mg carprofen per kg bodyweight per day.
An initial dose of 4 mg carprofen per kg bodyweight per day given as a single daily dose or in two equally divided doses may, subject to clinical response, be reduced after 7 days to 2 mg carprofen/kg bodyweight/day given as a single dose.
Duration of treatment will be dependant upon the response seen. Long term treatment should be under regular veterinary supervision.
To extend analgesic and anti-inflammatory cover post-operatively, parenteral preoperative treatment may be followed with carprofen tablets at 4 mg/kg/day for up to 5 days.
Do not exceed the stated dose.

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

No signs of toxicity appeared when dogs were treated with carprofen at levels up to 6 mg/kg twice daily for 7 days (3 times the recommended dose rate of 4 mg/kg) and 6 mg/kg once daily for a further 7 days. (1.5 times the recommended dose rate of 4 mg/kg). 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 is a member of the 2-arylpropionic acid group of non-steroidal anti-inflammatory drugs (NSAIDs), and possesses anti-inflammatory, analgesic and antipyretic activity. Carprofen is a chiral drug. 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

After oral administration, carprofen is well absorbed in the dogs. Following the administration of the veterinary medicinal product in dogs, a mean C_{max} (maximum concentration in serum) of 15.8 ng/ml and 12.2 ng/ml was achieved at approximately 2 hours and 1.7 hours for carprofen R(-) and carprofen

S(+), respectively. For both enantiomers, the mean half-life was approximately 6 hours. The analgesic effect from each dose persists for at least 12 hours.
Carprofen has a small volume of distribution and a low systemic clearance. It is highly bound to plasma protein.
Carprofen is metabolised in the liver by conjugation and oxidation. The excretion of the glycuronide conjugate is mainly faecal after biliary excretion.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 5 years.
Shelf-life of the half tablets: use immediately.

5.3 Special precautions for storage

Store in the original package.
Protect from light.
Store in a dry place.

5.4 Nature and composition of immediate packaging

Blister packs made up of a PVC/PVdC (250 µm/40 g/m^2) with a 20 µm Hard Temper Aluminium Foil in a cardboard box. Blister containing 6, 10 or 14 tablets.

Pack sizes:
6 tablets: A cardboard box of 1 blister. Each blister contains 6 tablets.
10 tablets: A cardboard box of 1 blister. Each blister contains 10 tablets.
14 tablets: A cardboard box of 1 blister. Each blister contains 14 tablets.
20 tablets: A cardboard box of 2 blisters. Each blister contains 10 tablets.
28 tablets: A cardboard box of 2 blisters. Each blister contains 14 tablets.
30 tablets: A cardboard box of 3 blisters. Each blister contains 10 tablets.
42 tablets: A cardboard box of 3 blisters. Each blister contains 14 tablets.
50 tablets: A cardboard box of 5 blisters. Each blister contains 10 tablets.
56 tablets: A cardboard box of 4 blisters. Each blister contains 14 tablets.
60 tablets: A cardboard box of 6 blisters. Each blister contains 10 tablets.
70 tablets: A cardboard box of 5 blisters with each blister containing 14 tablets or a cardboard box of 7 blisters with each blister containing 10 tablets.
84 tablets: A cardboard box of 6 blisters. Each blister contains 14 tablets.
98 tablets: A cardboard box of 7 blisters. Each blister contains 14 tablets.
100 tablets: A cardboard box of 10 blisters. Each blister contains 10 tablets.
140 tablets: A cardboard box of 10 blisters with each blister containing 14 tablets or a cardboard box of 14 blisters with each blister containing 10 tablets.
180 tablets: A cardboard box of 18 blisters. Each blister contains 10 tablets.
200 tablets: A cardboard box of 20 blisters. Each blister contains 10 tablets.
250 tablets: A cardboard box of 25 blisters. Each blister contains 10 tablets.
280 tablets: A cardboard box of 28 blisters with each blister containing 10 tablets or a box of 20 blisters with each blister containing 14 tablets.
300 tablets: A cardboard box of 30 blisters. Each blister contains 10 tablets.
500 tablets: A cardboard box of 50 blisters. Each blister contains 10 tablets.
1000 tablets: A cardboard box of 100 blisters. Each blister contains 10 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

Chanelle Pharmaceuticals Manufacturing Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10987/117/003

8. DATE OF FIRST AUTHORISATION

28/08/2015

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

25/09/2026

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).