1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rofeniflex 100 mg Tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains :
Active substance:
Carprofen 100.0 mg

Excipients:

Qualitative composition of excipients and other constituents
Lactose Monohydrate
Microcrystalline Cellulose
Silica Colloidal anhydrous
Grilled Meat Flavour 2007.01
Magnesium Stearate

A white to off white round shape tablets with a cross break line on one side.

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 following soft tissue surgery.

3.3 Contraindications

Do not use in cats.
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.
Refer to section 3.7.

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 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.
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.

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

In case of accidental ingestion, seek medical adviceand 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], soft stool/diarrhea[2], Blood in faeces[2], loss of appetite[2], lethargy[2]

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

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:

Laboratory studies in 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.

3.9 Administration routes and dosage

For oral use.
4 mg carprofen per kg body weight 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 dependent 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 2 days as required.
Do not exceed the stated dose.

The tablets can be divided into halves or quarters. Divided tablets should be used at the next administration. Any divided tablets remaining after the last administration of the veterinary medicinal product should be discarded.

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 with the S(+) enantiomer being more active than the R(-) enantiomer. 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 μg/ml and 12.2 μg/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

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Return any divided tablets to the blister pack or container and use within 72 hours.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

i) White High Density Polyethylene (HDPE) Twist-off plastic containers with child proof tamper evident Polypropylene white twist-off closures.
ii) Blister packs made up of a PVC/PVdC (250 µm/40 g/m^2) with a 20 mu Hard Temper Aluminium Foil.

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

Pack sizes for containers:
The container pack sizes and volumes are as follows:

100mg:

Pack size	Container volume
6, 10, 14	15 ml
20, 28, 30	35 ml
42, 50	60 ml
60, 70	75 ml
84, 98	100 ml
100	150 ml
140, 180, 200	200 ml
250	250 ml
280, 300	400 ml

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)

VPA10987/067/003

8. DATE OF FIRST AUTHORISATION

02/06/2006

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

20/08/2026

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).