SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rofeniflex 100 mg Tablets for dogs (Ireland)
Canidryl 100 mg Tablets for dogs (Germany & United Kingdom)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient
Carprofen 100.0 mg/tablet

Excipients
For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

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

The tablets can be divided into halves or quarters.

4. CLINICAL PARTICULARS

4.1 Target Species

Dogs.

4.2 Indications for use, specifying the 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.

4.3 Contraindications

Do not use in cats.
Do not use in case of hypersensitivity to 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 4.7.

4.4 Special warnings for each target species

Refer to Sections 4.3 and 4.5

4.5 Special precautions for use

Special precautions for use in animals
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 the event of accidental ingestion of the tablets, seek medical advice and show the doctor the package leaflet. Wash hands after handling the product.

4.6 Adverse reactions (frequency and seriousness)

Typical undesirable effects associated with NSAIDs, such as vomiting, soft faeces/diarrhea, faecal occult blood, loss of appetite and lethargy have been reported. These adverse reactions occur generally within the first treatment week and are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal.
If adverse reactions occur, use of the product should be stopped and the advice of a veterinarian should be sought.
As with other NSAIDs there is a risk of rare renal or idiosyncratic hepatic adverse events.

4.7 Use during pregnancy, lactation or lay

Studies in laboratory species (rat and rabbit) 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.

4.8 Interaction with other medicinal products and other forms of interaction

Carprofen must not be administered with glucocorticoids.
Refer also to section 4.5

4.9 Amounts to be administered and administration route

For oral administration.
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 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 4mg/kg/day for 2 days.
Do not exceed the stated dose.
Return any divided tablets to the blister pack or container and use within 72 hours. Divided tablets should be used at the next administration. Any divided tablets remaining after the last administration of the product should be discarded.

4.10 Overdose (symptoms, emergency procedures, antidotes) (if necessary)

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 4mg/kg) and 6mg/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.

4.11 Withdrawal Period(s)

Not applicable.

5. PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Non-steroidal anti-inflammatory drug.
ATCVet Code: QM01AE91.

5.1 Pharmacodynamic Properties

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.

5.2 Pharmacokinetic particulars

After oral administration, carprofen is well absorbed in the dogs. Following the administration of Rimifin tablets in dogs, a mean Cmax (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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose Monohydrate
Microcrystalline Cellulose
Silica Colloidal anhydrous
Grilled Meat Flavour 2007.01
Magnesium Stearate

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale is 3 years.

Return any divided tablets to the blister pack or container and use within 72 hours.

6.4 Special precautions for storage

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

6.5 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 (250µm/40g/m^2) with a 20mu 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	15ml
20, 28, 30	35ml
42, 50	60ml
60, 70	75ml
84, 98	100ml
100	150ml
140, 180, 200	200ml
250	250ml
280, 300	400ml

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal or unused veterinary medicinal product or waste materials

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co. Galway
Ireland

8. MARKETING AUTHORISATION NUMBER

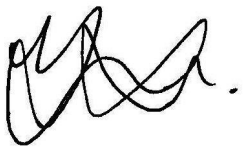
Vm 08749/4011

9. DATE OF FIRST AUTHORISATION

12 December 2006

10. DATE OF REVISION OF THE TEXT

December 2019



Approved: 19 December 2019