Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprieve 5 %w/v Small Animal Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains :

Active substances

Carprofen	50	mg

Excipients:

Benzyl Alcohol	10 mg	(preservative)
Sodium Formaldehyde Sulphoxylate	2.5 mg	(antioxidant)

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.
A clear colourless to pale yellow solution for injection

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs and cats

4.2 Indications for use, specifying the target species

In the dog: For the control of post-operative pain following orthopaedic and soft tissue surgery.
In the cat: For the treatment of post-operative pain following soft tissue surgery.

4.3 Contraindications

Do not administer by intramuscular injection.
Do not administer 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.Do not use in animals suffering from cardiac, hepatic or renal disease, where there is a possibility of gastrointestinal ulceration or bleeding, or hypersensitivity to the product.

4.4 Special warnings for each target species

Refer to statements under Sections 4.3 and 4.5.

4.5 Special precautions for use

Special precautions for use in animals

Do not exceed the recommended dose or duration of treatment. In the cat, due to the longer half-life, and narrower therapeutic index, particular care should be taken not to exceed the recommended dose.

Use in any animals less than 6 weeks of age, or in aged animals, may involve additional risk. If such use cannot be avoided, such animals may require a reduced dosage and careful clinical management.

Avoid use in any dehydrated, hypovolaemic or hypotensive animal, 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

Carprofen, in common with other NSAIDs, has been shown to exhibit photosensitising potential in laboratory studies.Avoid skin contact with the product. Wash off any splashes immediately. Wash hands after use.Care should be taken when handling the product to avoid accidental self-administration or skin contact.

4.6 Adverse reactions (frequency and seriousness)

As with other NSAIDs there is a risk of rare renal or idiosyncratic hepatic adverse events.

4.7 Use during pregnancy, lactation or lay

In the absence of any specific studies in pregnant target animals such use is not indicated

4.8 Interaction with other medicinal products and other forms of interactions

Do not administer 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.
Concurrent administration of potential nephrotoxic drugs should be avoided

4.9 Amounts to be administered and administration route

For intravenous or subcutaneous administration in the dog or intravenous administration in that cat.

In the dog, the recommended dosage is 4 mg/kg (1 ml/12.5kg) bodyweight.
In the cat, the recommended dosage is 4 mg/kg (0.24 ml/3 kg) bodyweight. Use of a 1 ml graduated syringe is recommended to measure the dose accurately.

For administration on a single occasion perioperatively. It is recommended that the product be given pre-operatively, either at the time of pre-medication or induction of anaesthesia.

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

The product is well tolerated at doses up to 3 times the recommended dose for dogs and 2 times the recommended dose for cats.
Typically, clinical signs of carprofen toxicity are associated with gastrointestinal ulceration and include anorexia, emesis, diarrhoea, faecal occult blood and weight loss. 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

ATC Vet Code : QM01AE91

Carprofen, (±)-6-chloro-α-methylcarbazole-2-acetic acid, is a nonsteroidal 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 C2 of the propionic moiety and therefore, exists in 2 sterioisomeric forms, the (+) - S and (-) - R enantiomers.

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

Following subcutaneous administration of 4 mg carprofen/kg to dogs, peak plasma concentrations of 12.6 microgram/ml were achieved in 3 hours.

Bioavailability following subcutaneous administration is in the range 90-100%. The volume of distribution is small with the highest drug concentrations occurring in plasma. Ratios of tissue to plasma concentration are less than one which is consistent with a high level of binding of carprofen to plasma proteins.
Following intravenous administration of carprofen to cats a half-life ($t_{½}$) of 20.1±16.6 hours was observed. The elimination half-life of carprofen ranged from 9 to 49 hours.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

L-Arginine
Lutrol F68
Benzyl Alcohol
Sodium Formaldehyde Sulphoxylate
Water for Injection

6.2 Major incompatibilities

In the absence of incompatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf-life after first opening the container: 28 days.

6.4 Special precautions for storage

Do not store above 25^{o}C.

6.5 Nature and composition of immediate packaging

20 ml multidose amber glass (Grade 1) sealed with 20 mm bromobutyl bungs and 20 mm aluminium seals.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22664/069/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30 September 2005
Date of last renewal: 29 September 2010

10 DATE OF REVISION OF THE TEXT

January 2019