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

Active Substance:	% w/v
Carprofen.	5.0

Excipients:

Benzyl Alcohol	1.0 (preservative)
Sodium Formaldehyde Sulphoxylate	0.25 (antioxidant)

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for Injection
A clear colourless to pale yellow solution

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and Cats

4.2 Indications for use, specifying the target species

In the dog it is indicated for the control of post-operative pain and inflammation following orthopaedic and soft tissue (including intra-ocular) surgery. In the cat it is indicated for the treatment of post operative pain following surgery.

4.3 Contraindications

Do not administer by intramuscular injection.
Do not exceed the recommended dose or duration of treatment.
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. As with other NSAIDs there is a risk of rare renal or idiosyncratic hepatic adverse events.

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

Special Warnings for each target species

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

4.5 Special precautions for use

(i) Special precautions for use in animals

Do not use in cats less than 5 months of age. Use in dogs less than 6 weeks of age, or in aged dogs and cats, 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.

(ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals

Care should be taken when handling the product to avoid accidental self-injection and skin contact. If skin contact occurs wash any product from the skin immediately. Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

"Typical undesirable effects associated with NSAIDs such as vomiting, soft faeces/diarrhoea, faecal occult blood, loss of appetite and lethargy have been reported in very rare instances. These adverse reactions 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, idiosyncratic hepatic or gastro-intestinal tract adverse events.

Rarely reactions at the injection site may be observed following subcutaneous injection."

"The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)."

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 interaction

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

In the dog, the recommended dosage is 4mg/kg (1ml/12.5kg) bodyweight, by intravenous or subcutaneous injection, best given pre-operatively, either at the time of premedication or induction of anaesthesia.
Clinical trial evidence in dogs suggests that only a single dose of carprofen is required in the first 24 hours peri-operatively; if further analgesia is required within this period, a single half-dose (2mg/kg) of carprofen may be given to dogs as necessary.
In the cat, the recommended dosage is 4mg/kg (0.24ml/3kg) bodyweight as a single dose by subcutaneous or intravenous injection, best given pre-operatively at the time of anaesthesia. In the cat, due to the longer half-life, and narrower therapeutic index, particular care should be taken not to exceed the recommended dose and the use of a 1ml graduated syringe is recommended to measure the dose accurately.

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

Carprofen is well tolerated up to 3 times the recommended dose for dogs and up to twice the recommended dose for cats.

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

Not applicable

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antinflammatory & antirheumatic products-Non –steroids.

ATC Vet Code: QM01AE91

5.1 Pharmacodynamic properties

Carprofen (CPF), (±)-6-chloro-α-methylcarbazole-2-acetic acid, is a nonsteroidal anti-inflammatory drug (NSAID) with analgesic and anti-pyretic properties. 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 sterioisomeric forms, the (+)-S and (-)-R enantiomers.

The mechanism of action of carprofen is unclear, there are two principal theories. One proposes that carprofen is a selective inhibitor of the cyclo-oxygenase isoenzyme, COX-2. The second hypothesis that carprofen is a weak inhibitor of both cyclo-oxygenase isoforms, COX-1 and COX-2, and that it acts, at least partially, by some other unknown mechanism.

5.2 Pharmacokinetic properties

Absorption of carprofen is reported to be rapid and complete in the dog. The volume of distribution is small with the highest drug concentrations observed in plasma, which has been ascribed to a high degree of binding to plasma protein. In the cat, following intravenous or subcutaneous administration, the clearance and volume of distribution were greater and elimination half-life was shorter for S(+) carprofen. Bioavailability after subcutaneous dosing was complete.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 Years

Shelf life after opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Do not store above 25°C.
Protect from light.
Following withdrawal of the first dose, use the product with 28 days.

6.5 Nature and composition of immediate packaging

Carton containing 1 x 20 ml multidose amber glass (type 1) vial with 20 mm bromobutyl bungs and 20 mm aluminium seals.

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

Any unused product or waste material should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down,
BT35 6JP
Northern Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 02000/4229

9. DATE OF RENEWAL OF THE AUTHORISATION

28 July 2010

10. DATE OF REVISION OF THE TEXT

February 2019

Approved: 28 February 2019