Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprosol 50 mg/ml solution for injection for dogs and cats.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:	
Active substance:	
Carprofen	50.0 mg
Excipients:	
Benzyl alcohol (E1519)	15.0 mg

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.
Clear brownish-yellow solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs, cats.

4.2 Indications for use, specifying the target species

Dog: For the control of post-operative pain and inflammation following orthopaedic and soft tissue (including intra-ocular) surgery.

Cat: For the control of post-operative pain following surgery.

4.3 Contraindications

Do not use in animals suffering from cardiac, hepatic or renal disease or gastrointestinal problems, where there is a possibility of gastrointestinal ulceration or bleeding, or hypersensitivity to carprofen or any other NSAIDs or any excipients of this product.
Do not administer by intramuscular injection.
Do not use after surgery which was associated with considerable blood loss.
Do not use in cats on repeated occasions.
Do not use in cats less than 5 months of age.
Do not use in dogs less than 10 weeks of age.
See also section 4.7, as the product is contraindicated during pregnancy and lactation.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Do not exceed the recommended dose or duration of treatment.
Use in aged dogs and cats may involve additional risk. If such a use cannot be avoided, animals may require a reduced dosage and careful clinical management.
Avoid use in dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of increased renal toxicity.
Concurrent administration of potentially 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 the animals

Persons with known hypersensitivity to the active substance should avoid contact with the product.
Care should be taken to avoid accidental self-injection. In case of accidental self-injection seek medical advice immediately and show the package leaflet or the label to the physician.
Carprofen, in common with other NSAIDs, has been shown to exhibit photosensitising potential in laboratory studies.
Avoid contact with skin and eyes. Wash off any splashes immediately with clean, running water. Seek medical attention if irritation persists.

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. 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.
Occasionally reactions at the injection site may be observed following subcutaneous injection.

4.7 Use during pregnancy, lactation or lay

Laboratory studies in laboratory animals (rat, 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 dogs or cats during pregnancy or lactation.

4.8 Interaction with other medicinal products and other forms of interaction

Carprofen should not be administered concurrently, or within 24 hours of another NSAID, or in conjunction with glucocorticosteroids. Carprofen is highly bound to plasma proteins and may compete with other highly bound drugs which can lead to toxic effects. Hence, concurrent administration with potentially nephrotoxic drugs should be avoided.

4.9 Amounts to be administered and administration route

Dog:
4 mg/kg (1 ml/12.5 kg) bodyweight, by intravenous or subcutaneous injection, best given pre-operatively, either at the time of premedication or induction of anaesthesia.
To extend analgesic and anti-inflammatory cover post-operatively, parenteral therapy may be followed with Carprofen tablets at 4 mg/kg/day for up to 5 days.

Cat:
4 mg/kg (0.08 ml/1.0 kg) bodyweight by intravenous or subcutaneous injection, best given pre-operatively, either at the time of premedication or induction of anaesthesia. Due to the longer half life in cats and narrower therapeutic index particular care should be taken not to exceed or repeat the recommended dose and the use of a 1 ml graduated syringe is recommended to measure the dose accurately. The parenteral therapy may not be followed with Carprofen tablets.

The stopper should not be punctured more than 20 times.

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

There is no specific antidote for carprofen overdosage. General symptomatic treatment, as is usual for clinical overdosage with NSAIDs, should be applied.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anti-inflammatory and anti-rheumatic products, non-steroids
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 properties.

As with most other NSAIDs, carprofen is an inhibitor of the enzyme cyclo-oxygenase of the arachidonic acid cascade. However, the inhibition of prostaglandin synthesis by carprofen is slight compared to its anti-inflammatory and analgesic properties. At therapeutic doses in the dog and cat, inhibition of the products of cyclo-oxygenase (prostaglandins and thromboxanes) or lipoxygenase (leucotrienes) has been absent or slight.

5.2 Pharmacokinetic properties

Following a single subcutaneous dose of 4 mg carprofen/kg in dogs, the maximum plasma concentration (C_{max}) of 16.0 µg/ml was reached after (T_{max}) 4-5 hours.
In cats the maximum plasma concentration (C_{max}) of 26.0 µg/ml was reached after approximately (T_{max}) 3-4 hours.
The bioavailability is 85% in dogs and more than 90% in cats.
Carprofen has a plasma elimination half-life of 10 hours in dogs and 20 hours at cats.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol (E1519)
Arginine
Glycocholic acid
Lecithin
Sodium hydroxide (for pH adjustment)
Hydrochloric acid 10% (for pH adjustment)
Water for injections

6.2 Incompatibilities

In the absence of compatibility 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 immediate packaging: 28 days.

6.4 Special precautions for storage

Store in a refrigerator (2°C - 8°C). Do not freeze.
Keep the bottle in the outer carton in order to protect from light.

6.5 Nature and composition of immediate packaging

20 ml amber glass bottles (Type I) with bromobutyl rubber stopper, covered with an aluminum cap.
The vials are packed singly in a cardboard box.

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

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

7 MARKETING AUTHORISATION HOLDER

CP-Pharma Handelsgesellschaft mbH
Ostlandring 13
31303 Burgdorf
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10810/012/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 31st May 2013

10 DATE OF REVISION OF THE TEXT

June 2015