SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dolocarp flavour, 20 mg, chewable tablets for dogs
Carprofen

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Each chewable tablet contains:
Carprofen 20 mg

Excipients:
Liver flavour liquid 1 mg
Special dry flavour vegetarian 10 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Chewable tablet
Beige-brown tablets with a break-line.
The chewable tablet can be divided in two halves.

4. CLINICAL PARTICULARS

4.1 Target species

Dog

4.2 Indications for use, specifying the target species

Reduction of inflammation and pain caused by acute and chronic musculoskeletal disorders (e.g. osteoarthritis). As a follow up to parenteral analgesia in the management of post operative pain.

4.3 Contraindications

Do not use in cats.
Do not use in pregnant or lactating bitches.
Do not use in cases of hypersensitivity to active substance, to other NSAIDs and to any of the excipients.
Do not use in animals suffering from cardiac, hepatic or renal disease, where there is a possibility of gastrointestinal ulceration or bleeding or where there is evidence of a blood dyscrasia.

4.4 Special warnings for each target species

None.

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 use cannot be avoided, such dogs may require a reduced dosage and careful clinical management.
Due to the good palatability of the chewable tablet, they should be stored in a safe place out of the reach of animals. Intake of doses exceeding the recommended number of chewable tablets may lead to severe adverse effects. If this is the case, seek veterinary assistance immediately.
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 and glucocorticoids 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.
Exposure to intense light during treatment may lead to photodermatitis in animals with low skin pigmentation. Such adverse reactions with carprofen have occurred in laboratory animals and humans. Although skin reactions of this kind have not yet been observed in dogs, they cannot be ruled out at present.

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

Carprofen may rarely cause a photosensitive skin allergy in some people. Avoid skin contact with the product.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet to the physician.
Wash hands after handling the product.

4.6 Adverse reactions (frequency and seriousness)

Typical undesirable effects associated with NSAIDs, such as vomiting, soft faeces/diarrhoea, faecal occult blood (visible black discolouration of the faeces), kidney dysfunction (increased thirst, increased or reduced urine volume) 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. Temporary increase in ALT values is possible. Very occasionally, cases of liver damage and liver dysfunction can occur.

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

Do not administer NSAIDs and glucocorticoids concurrently or within 24 hours of each other. Concurrent administration of potential nephrotoxic drugs should be avoided. Refers also to section 4.5.

Carprofen has a high affinity for plasma protein (99% binding). For this reason, it should not be administered simultaneously with other substances which also demonstrate a high degree of plasma protein binding. In the case of pre-treatment with steroidal or non-steroidal anti-inflammatories, there must be a treatment-free period as the severity of possible adverse effects could otherwise be intensified.

4.9 Amounts to be administered and administration route

Chewable tablet for oral use. The stated dose should not be increased.
Administer the dose of 4.0 mg per kg body weight once daily. In cases of long term treatment the initial dose may, subject to clinical response, be reduced to 2 mg per kg body weight once daily.
Most dogs will voluntarily ingest the product.
The treatment period depends on the clinical development of the disease. Long-term treatment should only be performed under veterinary supervision.
The tablets can be broken along the breakline.

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

In case of the typical side effects of nonsteroidal anti-inflammatory drugs such as gastrointestinal disorders (anorexia, vomiting, diarrhoea, ulceration), gastrointestinal bleeding (indicated by a blackening of the faeces) or signs of kidney dysfunction (increased thirst, increased or reduced urine volume), treatment should be discontinued immediately and the advice of a veterinarian sought.

Although studies investigating the safety of the product at overdose have been performed, 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 PROPERTIES

Pharmacotherapeutic group: Antiinflammatory and antirheumatic products, non-steroid, propionic acid derivative

ATCvet code: QM 01 AE 91

5.1 Pharmacodynamic properties

Carprofen is a non-steroidal anti-inflammatories (NSAID) and belongs to the group of 2-arylpropionic acids. It has an anti-inflammatory, analgetic and antipyretic effect.

Like most NSAIDs, carprofen is a specific cyclooxygenase inhibitor in the arachidonic acid cascade. Prostaglandin synthesis is interrupted as a result. Prostaglandins play a significant role in the development of inflammatory reactions and as a mechanism for protecting the mucous membrane of the gastro-intestinal tract against ulceration. Cyclooxygenase (COX) has two isoenzymes, COX-1 and COX-2. The COX-1 enzyme is constantly in the blood and has autoregulatory functions (e.g. protection of the mucous membrane in the gastro-intestinal tract and the protection of the kidneys).

In contrast, COX-2 is not constantly in the blood. This enzyme is believed to be induced by the inflammatory process. On the basis of this supposition, it is concluded that the degree of COX-1 inhibition determines the rate of gastro-intestinal ulceration and that the ratio of isoenzymes to one another determines the rate of adverse reaction and/or the effectiveness. Carprofen has a COX-2 : COX-1 ratio of 1.0.

The precise remaining modes of action of carprofen are not yet fully understood.

5.2 Pharmacokinetic particulars

Resorption is fast and complete. The volume of distribution is low since plasma protein binding is 99%. Following the administration of the product in dogs, a mean Cmax (maximum concentration in serum) of 23,2 µg/ml was achieved at approximately 3 hours for Carprofen.

In the case of dogs, carprofen is secreted with the faeces via the bile primarily (60 – 70%) in metabolised form (glucuronic acid ester and two phenolic metabolites). The mean half-life is (t1/2) eight hours.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize starch
Lactose monohydrate
Sucrose
Wheat germ hydrolysate powder
Magnesium stearate
Calcium hydrogen phosphate, anhydrous
Soy protein hydrolysate powder - pure
Povidone
Liver flavour liquid
Silica colloidal anhydrous
Special dry flavour vegetarian

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale:	5 years
Shelf-life after first opening the tablet container:	1 year
Shelf life of halved tablets:	48 hours

6.4. Special precautions for storage

Store in a dry place.
Keep the tablet container tightly closed.

6.5 Nature and composition of immediate packaging

White tablet container made of high-density polyethylene with a childproof seal in a cardboard box. The product is closed with a white polypropylene cap with or without a desiccant.

Pack sizes: 20 and 100 tablets

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product 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

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<{DD/MM/YYYY}>

10. DATE OF REVISION OF THE TEXT

{MM/YYYY}

11. PROHIBITION OF SALE, SUPPLY AND/OR USE

[To be completed in accordance with national requirements after conclusion of the MR phase].