

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rimadyl Palatable Tablets for dogs 50 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 50mg Carprofen.

For the full list of all other excipients see section 6.1

3. PHARMACEUTICAL FORM

Tablet.

A light brown square tablet with "R" engraved on one side and bisected on the other side.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

For analgesia and reduction of chronic inflammation, for example in degenerative joint disease in the dog.

The tablets can also be used in the management of post-operative pain.

4.3 Contraindications

Do not exceed the stated dose.

The elimination time of NSAIDs, including carprofen, in the cat is longer than in the dog and the therapeutic index is narrower. In the absence of specific data use in the cat is contra-indicated.

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 blood dyscrasia or hypersensitivity to the product. As with other NSAIDs there is a risk of rare idiosyncratic renal or hepatic adverse events.

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.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

i) 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, such dogs may require a reduced dosage and careful clinical management.

Avoid use in any dehydrated, hypovolaemic or hypotensive dog, as there is a potential rise of increased renal toxicity.

Concurrent administration of potential nephrotoxic drugs should be avoided.

NSAID's 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

In the event of accidental ingestion of the tablets, seek medical advice and show the doctor what has been taken. 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, loss of appetite and lethargy have been reported. These adverse reactions generally occur 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

In the absence of any specific studies in pregnant bitches, such use is not indicated.

4.8 Interaction with other medicinal products and other forms of interaction

No significant drug interactions have been reported for carprofen. The acute toxicity of carprofen in animals was not significantly affected in tests with fifteen commonly used (or commonly available) drugs. These were acetylsalicylic acid, amphetamine, atropine, chlorpromazine,

diazepam, diphenhydramine, ethyl alcohol, hydrochlorothiazide, imipramine, meperidine, propoxyphene, pentobarbital, sulfoxazole, tetracycline and tolbutamide. (Jeunet, 1982).

Whilst carprofen and warfarin may both be bound to plasma proteins, they may be used concurrently provided the clinical situation is carefully monitored since it has been shown that they bind to two distinct sites on human and bovine serum albumin [Sudlow et al (1976), Crouthamel and Popick (1979) and Jeunet (1982)].

4.9 Amounts to be administered and administration route

For oral administration. The tablets are palatable and willingly consumed by most dogs when offered.

An initial dose of 2 to 4 mg carprofen per kg bodyweight per day is recommended to be given as a single dose or in two equally divided doses.

Subject to clinical response, the dose may be reduced after 7 days to 2 mg carprofen/kg bodyweight/day given as a single dose.

To extend analgesic and anti-inflammatory cover post-operatively, parenteral therapy with Rimadyl Small Animal Injection may be followed with the tablets at 4mg/kg/day for up to 5 days.

Duration of treatment will be dependent upon the response seen. Long term treatment should be under regular veterinary supervision.

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

There is no specific antidote for carprofen overdosage but general supportive therapy, as applied to clinical overdosage with NSAID's, should be applied.

4.11 Withdrawal period

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

ATC Vet code: QM01AE91 Anti-inflammatory

Mechanism of Action

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, 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. At therapeutic doses in the dog inhibition of the products of cyclo-oxygenase (prostaglandins and thromboxanes) or lipoxygenase (leucotrienes) has been absent or slight.

Since prostaglandin inhibition is thought to underlie the principal toxic side effects of NSAIDs, lack of cyclo-oxygenase inhibition may explain the excellent gastro-intestinal and renal tolerance of carprofen seen in this species. The precise mode of action of carprofen is not clear.

Following repeated therapeutic dosing for 8 weeks, carprofen has been shown to have no detrimental effect on chronically arthritic canine cartilage in a model of canine osteoarthritis.

In addition, therapeutic concentrations of carprofen have been demonstrated (*in vitro*) to increase proteoglycan synthesis in chondrocytes from canine arthritic cartilage.

Stimulation of proteoglycan synthesis will narrow the difference between the rate of degeneration and regeneration of cartilage matrix resulting in a slowing of the progression of cartilage loss.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Pig Liver Powder
Vegetable Protein Hydrolyzed
Maize Starch
Lactose Monohydrate
Confectioner's Sugar
Wheat Germ
Calcium Hydrogen Phosphate Anhydrous
Corn Syrup 81.5% solids
Gelatin
Magnesium Stearate
Water Purified*

* Not present in the finished product.

6.2 Incompatibilities

None known.

6.3 Shelf-life

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

6.4 Special precautions for storage

Store in a dry place. Protect from light. Do not store above 25°C.
Due to the palatable nature of the tablets, store in a secure location.
Severe adverse reaction may occur if large quantities are ingested. If you suspect your dog has consumed Rimadyl Palatable Tablets above the labelled dose, please contact your veterinarian.

6.5 Nature and composition of immediate packaging

Square white high-density polyethylene bottle fitted with a child resistant polypropylene closure.

Pack sizes: 14, 20, 30, 50, 60, 100 and 180 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, if appropriate

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

Zoetis UK Limited
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8. MARKETING AUTHORISATION NUMBER

Vm 42058/5168

9. DATE OF THE FIRST AUTHORISATION

14 February 2003

10. DATE OF REVISION OF THE TEXT

November 2024

Gavin Hall

Approved 14 November 2024