Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Rimadyl Palatable Tablets 20 mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 20 mg Carprofen.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Chewable tablets.

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.
Rimadyl Palatable 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 the use of Rimadyl Palatable Tablets 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.
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

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 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

None.

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 dissapear following termination of 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 interactions

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, sulfisoxazole, tetracycline and tolbutamide. 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.

4.9 Amounts to be administered and administration route

For oral administration. Rimadyl Palatable 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 Rimadyl Palatable Tablets at 4 mg/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 NSAIDs, should be applied.

4.11 Withdrawal period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiinflammatory and antirheumatic product, carprofen. 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 activity.

Carprofen, like most other NSAIDs is an inhibitor of the enzyme cyclo-oygenase 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.

5.2 Pharmacokinetic particulars

As with other NSAIDs, carprofen accumulates in acute inflammatory exudates and is cleared more slowly from this fluid than from plasma.
The analgesic action has been proven to extend for approximately 24 hours. Analgesia in this species has been correlated with plasma concentrations in excess of 1.5 µg/ml. This level is achieved for around 12 hours in plasma, although mean exudate concentrations are maintained above this level for at least 24 hours.
Carprofen is a chiral drug with the S(+) enantiomer being more active than the R(-) enantiomer. There is no chiral inversion between the enantiomers *in-vivo*.
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 proteogylcan synthesis will narrow the difference between the rate of degradation and regeneration of cartilage matrix resulting in a slowing of the progression of cartilage loss.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Spray dried pork liver powder
Hydrolyzed vegetable protein
Maize starch
Lactose monohydrate
Confectioner's sugar
Wheat germ
Calcium hydrogen phosphate anhydrous
Corn syrup
Gelatine Type A
Magnesium stearate
Purified Water

6.2 Major 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.

6.5 Nature and composition of immediate packaging

Square white high-density polypropylene 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 products 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

Zoetis Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park, Loughlinstown
Co Dublin
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10387/059/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19th March 2004
Date of last renewal: 18th March 2009

10 DATE OF REVISION OF THE TEXT

April 2020