1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rimadyl Palatable Tablets 100 mg for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:
Carprofen 100 mg

Excipients:

Qualitative composition of excipients and other constituents
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

Light-brown tablet, debossed "R" on one side and bisected on the opposite side.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

For analgesia and reduction of chronic inflammation, for example in degenerative joint disease, in the dog. The veterinary medicinal product can also be used in the management of post-operative pain.

3.3 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 the veterinary medicinal product 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.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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.

Store in a secure location, due to the palatable nature of the veterinary medicinal product.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands after handling the product.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Dogs:

Rare (1 to 10 animals / 10,000 animals treated):	Gastric ulceration, Intestinal disorder[1] Hepatic disorder[2] Renal disorder[2]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Blood in faeces[3], Diarrhoea[3], Vomiting[3] Appetite loss[3], Lethargy[3]

[1] Reported as ulceration.
[2] As with any other NSAID. Reported as idiosyncrasy.
[3] Typical undesirable effects associated with NSAIDs that generally occur within the first treatment week and are in most cases transient and disappear 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.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing

authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
The use is not recommended during pregnancy.

3.8 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, 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.

3.9 Administration routes and dosage

Oral use.
The veterinary medicinal product is 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QM01AE91

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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 proteoglycan 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

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

5.3 Special precautions for storage

Do not store above 25 °C.
Protect from light.
Store in a dry place.

5.4 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.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.

7. MARKETING AUTHORISATION NUMBER

VPA10387/059/003

8. DATE OF FIRST AUTHORISATION

06/03/2015

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

30/07/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).