

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {BOTTLE LABEL}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rimadyl Palatable Tablets 50 mg

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:
Carprofen 50 mg

3. TARGET SPECIES

Dogs

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.
Oral use.

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

Exp. {mm/yyyy}

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.
Protect from light.
Store in a dry place.
Store in a secure location, due to the palatable nature of the veterinary medicinal product.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Rimadyl Palatable Tablets 20 mg for dogs
Rimadyl Palatable Tablets 50 mg for dogs
Rimadyl Palatable Tablets 100 mg for dogs

2. Composition

Each tablet contains:

Active substance:

20 mg, 50 mg or 100 mg Carprofen.

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

3. Target species

Dogs.

4. Indications for use

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

5. 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.

6. Special warnings

None.

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 rise 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:

Wash hands after handling the product.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy:

The use is not recommended during pregnancy.

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.

Overdose:

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

7. 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 NSAIDs. 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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Oral use.

An initial dose of 2 to 4 mg carprofen/kg bodyweight/day is recommended to be given in 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 administered 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 bodyweight/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.

9. Advice on correct administration

The veterinary medicinal product is palatable and willingly consumed by most dogs when offered.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25 °C.

Store in a dry place.

Protect from light.

Due to the palatable nature of the veterinary medicinal product, store in a secure location.

Severe adverse reactions may occur if large quantities are ingested. If you suspect your dog has consumed the veterinary medicinal product above the labelled dose, please call your veterinarian.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

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. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 60021/3014 (20 mg tablet)

Vm 60021/3015 (50 mg tablet)

Vm 60021/3013 (100 mg tablet)

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.

PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

Zoetis Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park
Loughlinstown
Dublin 18
D18 T3Y1
Ireland
Phone: +353 (0) 1 256 9800

Manufacturer responsible for batch release:

Zoetis Belgium
Rue Laid Burniat 1
1348 Louvain-La-Neuve
Belgium

17. Other information

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.

POM-V

Gavin Hall

Approved: 19 December 2025