PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {Bottle label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rimadyl Palatable Tablets for Dogs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains:
carprofen 100 mg

3. PHARMACEUTICAL FORM

Tablets

4. PACKAGE SIZE

14 tablets
30 tablets
100 tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

For analgesia and reduction of chronic inflammation.

7. METHOD AND ROUTE OF ADMINISTRATION

For full information see package leaflet.

Dosage: For oral administration.

Initial dose 2–4mg/kg/day as a single dose or in 2 equally divided doses.

After 7 days, subject to clinical response, dose may be reduced to 2mg/kg/day as a single daily dose.

Long term treatment should be under regular veterinary supervision.

8. WITHDRAWAL PERIOD

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9. SPECIAL WARNING(S), IF NECESSARY

Due to the palatable nature of Rimadyl Palatable Tablets, store in a secure location.

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

Store in a dry place.

Protect from light.

Do not store above 25°C.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only.

POM-V

To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited, Surrey

16. MARKETING AUTHORISATION NUMBERS

Vm 42058/4120

17. MANUFACTURER'S BATCH NUMBER

LOT:

PACKAGE LEAFLET FOR: Rimadyl Palatable Tablets for Dogs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Zoetis UK Limited
First Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

Manufacturer responsible for batch release:
Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
Belgium

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rimadyl Palatable Tablets for Dogs

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Rimadyl Palatable Tablets are light brown tablets scored down the middle containing as active ingredient 20 mg, 50 mg or 100 mg carprofen.

4. INDICATION(S)

For analgesia and reduction of chronic inflammation, for example in degenerative joint disease of the dog. Rimadyl Palatable Tablets can also be used in the management of post-operative pain.

5. CONTRAINDICATIONS

Do not administer other NSAID's concurrently or within 24 hours of each other. Some NSAID's may be highly bound to plasma proteins and compete with other highly bound drugs, which can lead to toxic effects.

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 a blood dyscrasia or hypersensitivity to the product.

Do not exceed the stated dose.

The elimination time of NSAID's, 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 contraindicated.

Use in dogs less than 6 weeks of age, or in aged dogs may involve additional risk. If such a use cannot be avoided, 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. 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. In the absence of any specific studies in pregnant target bitches, such use is not indicated.

6. ADVERSE REACTIONS

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.

7. TARGET SPECIES

Dogs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For oral administration.

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

Rimadyl Palatable Tablets are palatable and willingly consumed by most dogs when offered.

10. WITHDRAWAL PERIOD(S)

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11. SPECIAL STORAGE PRECAUTIONS

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

Due to the palatable nature of Rimadyl Palatable Tablets, store in a secure location. Severe adverse reactions may occur if large quantities are ingested. If you suspect your dog has consumed Rimadyl Palatable Tablets above the labelled dose, please call your veterinarian.

12. SPECIAL WARNINGS

Operator Warnings
In the event of accidental ingestion of the tablets, seek medical advice and show the doctor this leaflet. Wash hands after handling the product.

Keep out of the sight and reach of children.

For animal treatment only.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of used packaging in the household refuse. Unused product should be returned to the veterinary surgeon.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

April 2020

15. OTHER INFORMATION

Experimental and clinical evidence suggests that for carprofen in the dog gastro-intestinal tract ulceration is rare, and only occurs at dosages well above the therapeutic dose.

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.

Containers of:
14, 30 or 100 x 20 mg tablets
14, 30 or 100 x 50 mg tablets
14, 30 or 100 x 100 mg tablets

Not all pack sizes may be marketed.

POM-V

To be supplied only on veterinary prescription.

Vm 42058/4121 (20 mg tablet)
Vm 42058/4122 (50 mg tablet)
Vm 42058/4120 (100 mg tablet)

Approved 09 April 2020