PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {Bottle label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rimadyl Small Animal Solution for Injection 50 mg/ml

Carprofen

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Carprofen 50 mg/ml with benzyl alcohol 10 mg/ml as preservative.

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

20 ml

5. TARGET SPECIES

For use in dogs and cats

6. INDICATION(S)

For details of uses, dosage, contra-indications & warnings, see pack leaflet.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

-

8. WITHDRAWAL PERIOD

-

9. SPECIAL WARNING(S), IF NECESSARY

-

10. EXPIRY DATE

EXP {month/year}

Once opened use within 28 days.

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton.

Store in a refrigerator (2-8°C). Do not freeze.

Once broached, the product is stable for use at temperatures up to 25°C for 28 days.

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
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER

Vm 42058/4123

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rimadyl Small Animal Solution for Injection 50 mg/ml

Carprofen

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Carprofen 50 mg/ml with benzyl alcohol 10 mg/ml as preservative.

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

20 ml

5. TARGET SPECIES

For use in dogs and cats

6. INDICATION(S)

For further details of uses, dosage, contra-indications & warnings, see pack leaflet.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dosage:

Dogs: 4 mg/kg (1 ml/12.5 kg) bodyweight by intravenous or subcutaneous injection.

Cats: 4 mg/kg (0.24 ml/3 kg) bodyweight by subcutaneous or intravenous injection.

8. WITHDRAWAL PERIOD

-

9. SPECIAL WARNING(S), IF NECESSARY

-

10. EXPIRY DATE

EXP {month/year}

Once opened use within 28 days.

Once opened use by….

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton.

Store in a refrigerator (2-8°C). Do not freeze.

Once broached, the product is stable for use at temperatures up to 25°C for 28 days.

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
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER

Vm 42058/4123

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

PACKAGE LEAFLET FOR: Rimadyl Small Animal Solution for Injection 50 mg/ml

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

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

Manufacturer responsible for batch release:
Zoetis Belgium S.A.
Rue Laid Burniat 1
1348 Louvain-La-Neuve
Belgium

or

Zoetis Manufacturing & Research Spain, S.L.
Ctra. Camprodón s/n “la Riba”
Vall de Bianya
Girona 17813
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rimadyl Small Animal Solution for Injection 50 mg/ml

Carprofen

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Rimadyl Small Animal Solution for Injection 50 mg/ml is a clear, sterile, mixed micelle solution for injection containing carprofen 50 mg/ml and benzyl alcohol 10 mg/ml as preservative.

4. INDICATION(S)

Carprofen is a non-steroidal, anti-inflammatory drug (NSAID) with analgesic and anti-pyretic properties.

In the dog, it is indicated for the control of post-operative pain and inflammation following orthopaedic and soft tissue (including intra-ocular) surgery.

In the cat, it is indicated for the control of post-operative pain following surgery.

5. CONTRAINDICATIONS

Do not administer by intramuscular injection.

Do not exceed the stated dose or duration of treatment.

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 animals suffering from cardiac, hepatic or renal disease, where there is a possibility of gastro-intestinal ulceration or bleeding, or hypersensitivity to the product.

Use in any animal less than 6 weeks of age, or in aged animals may involve additional risk. If such use cannot be avoided, animals may require a reduced dosage and careful clinical management.

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

Concurrent administration of potential nephrotoxic drugs should be avoided.

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

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.

Carprofen should not be administered in conjunction with glucocorticoids.

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 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, idiosyncratic hepatic or gastro-intestinal tract adverse events. Rarely reactions at the injection site may be observed following subcutaneous injection.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)

- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

7. TARGET SPECIES

Dogs and cats.

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

In the dog, the recommended dosage is 4.0 mg/kg (1 ml/12.5 kg) bodyweight, by intravenous or subcutaneous injection.

In the cat, the recommended dosage is 4.0 mg /kg (0.24 ml/3 kg) bodyweight, by intravenous or subcutaneous injection.

9. ADVICE ON CORRECT ADMINISTRATION

Rimadyl Small Animal Solution for Injection 50 mg/ml is best given pre-operatively, either at the time of premedication or induction of anaesthesia. To extend analgesic and anti-inflammatory cover post-operatively, parenteral therapy may be followed with Rimadyl Tablets at 4 mg/kg/day for up to 5 days.

Rimadyl Small Animal Injection is best given pre-operatively at the time of induction of anaesthesia.

Clinical trial evidence in dogs and cats suggests that only a single dose of carprofen is required in the first 24 hours peri-operatively; if further analgesia is required within this period, a single half dose (2 mg/kg) of carprofen may be given to dogs (but not cats). Alternatively an opiate may be administered as necessary.

In the cat, due to the longer life, and narrower therapeutic index, particular care should be taken not to exceed the recommended dose and the use of a 1 ml graduated syringe is recommended to measure the dose accurately.

10. WITHDRAWAL PERIOD(S)

-

11. SPECIAL STORAGE PRECAUTIONS

Store in refrigerator (2-8°C). Do not freeze.

Once broached, the product is stable for use at temperatures up to 25°C for 28 days.

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

Shelf life after first opening the container: 28 days.

When the container is broached/opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided.

12. SPECIAL WARNING(S)

Operator Warnings
Avoid contact with skin and eyes. Wash off any splashes immediately with clean, running water. Seek medical attention if irritation persists. Care should be taken to avoid accidental self injection. If accidental self injection occurs, seek medical advice immediately.

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 any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

February 2023

15. OTHER INFORMATION

20 ml multidose amber glass vials.

Both carprofen and warfarin may be bound to plasma proteins. Limited evidence indicates that binding is at different sites, thus enabling concurrent use, but the situation must be monitored carefully.

Clinical trial evidence in dogs and cats suggests that only a single dose of carprofen is required in the first 24 hours peri-operatively; if further analgesia is required within this period, a single half-dose (2 mg/kg) of carprofen may be given to dogs (but not cats) as necessary.

POM-V

To be supplied only on veterinary prescription

Vm 42058/4123

Approved 01 March 2023