SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rimadyl Small Animal Solution for Injection 50 mg/ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient:	***mg/ml***
Carprofen	50.0

Preservative:	
Benzyl Alcohol	10.0

For the full list of all other excipients see section 6.1

3. PHARMACEUTICAL FORM

Solution for injection.
A clear, pale yellow solution.

4. CLINICAL PARTICULARS

4.1 Target species

Canine and feline.

4.2 Indications for use, specifying the target species

Dogs: For the control of post-operative pain and inflammation following orthopaedic and soft tissue (including intra-ocular) surgery.

Cats: For the control of post-operative pain following surgery.

4.3 Contraindications

Do not administer by intra-muscular injection.

Do not exceed the stated dose or the duration of treatment.

Do not use in animals suffering from cardiac, hepatic or renal disease, where there is a possibility of gastro-intestinal ulceration or bleeding 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 any animal less than 6 weeks of age, or in aged animals, may involve additional risk. If such a 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.

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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

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 self-injection. If accidental self-injection occurs, seek medical attention immediately.

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 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).

4.7 Use during pregnancy, lactation or lay

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

4.8 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, penobarbital, sulfisoxazole, tetracycline and tolbutamide. (Jeunet, 1982).

Rimadyl Small Animal Solution for Injection should not be administered concurrently, or within 24 hours of another NSAID, or in conjunction with glucocorticosteroids.

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 [Sudlow et al (1976), Crouthamel and Popick (1979) and Jeunet (1982)].

4.10 Amounts to be administered and administration route

Dogs: The recommended dosage is 4.0 mg/kg bodyweight (1 ml/12.5kg bodyweight), by intravenous or subcutaneous injection, 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 4mg/kg/day for up to 5 days.

Cats: The recommended dosage is 4 mg/kg (0.24ml/3.0kg bodyweight) by subcutaneous or intravenous injection, best given pre-operatively at the time of induction of anaesthesia. Due to the longer half life in cats 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.

Clinical trial evidence in dogs and cats suggests 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.

4.11 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 NSAID’s, should be applied.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Mechanism of Action

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-oxygenase 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, horse and cat, 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 these species. The precise mode of action of carprofen has not yet been fully elucidated.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

L Arginine
Glycocholic Acid
Lecithin (soya)
Sodium Hydroxide Pellets
Sodium Hydroxide
Benzyl Alcohol
Hydrochloric Acid
Water for Injections

6.2 Major Incompatibilities

None known.

6.3 Shelf-life

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

Shelf life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Store in a refrigerator (2 to 8^{o}C). Do not freeze. Once broached, the product is stable at temperatures up to 25^{o}C for 28 days.

6.5 Nature and composition of immediate packaging

20ml multidose amber (Type 1) vial of approximately 20mm diameter, capped with a grey butyl rubber stopper and aluminium seal.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
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KT22 7LP
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8. MARKETING AUTHORISATION NUMBER

Vm 42058/5222

9. DATE OF THE FIRST AUTHORISATION

04 February 1999

10. DATE OF REVISION OF THE TEXT

December 2025

Gavin Hall
Approved: 17 December 2025