Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Rimadyl Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance	
Carprofen	50 mg/ml
Excipients	
Benzyl Alcohol	10 mg/ml

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection. A clear, sterile, mixed micelle solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs and Cats.

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 or where there is evidence of blood dyscrasia or hypersensitivity to the product. As with other NSAIDs, there is a risk of rare renal or idiosyncratic hepatic adverse events.

4.4 Special warnings for each target species

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 1ml graduated syringe is recommended to measure the dose accurately.

4.5 Special precautions for use

Special precautions for use in animals

Use in any animals less than 6 weeks of age, or in aged animals, may involve additional risk. If such a use cannot be avoided, animals may require 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.

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

There are no special warnings for persons administering the product but care should be taken to avoid accidental self-injection.

4.6 Adverse reactions (frequency and seriousness)

As with other NSAIDs, there is a risk of rare renal or idiosyncratic hepatic adverse events.

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, pentobarbital, sufisoxazole, tetracycline and tolbutamide (Jeunet, 1982).

Rimadyl injection should not be administered concurrently, or within 24 hours of another NSAID.

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 Pepick (1979) and Jeunet (1982).

4.9 Amounts to be administered and administration route

Dogs: The recommended dosage is 4.0 mg carprofen/kg bodyweight (1ml/12.5 kg bodyweight), by intravenous or subcutaneous injection. Rimadyl Injection is best given pre-operatively, either at the time of premedication or induction of anaesthesia.

Cats: The recommended dosage is 4.0 mg/kg (0.24 ml/3.0 kg 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 1ml 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 perioperatively; if further analgesia is required in this period a half dose (2mg/kg) of carprofen may be given to dogs (but not to cats) as necessary.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

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 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 to carprofen seen in these species. The precise mode of action of carprofen is not clear.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

L-Arginine
Glycocholic Acid 100%
Sodium Hydroxide
Lecithin
Benzyl Alcohol
Hydrocholoric Acid
Water for Injection

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 36 months.
Shelf life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

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.

6.5 Nature and composition of immediate packaging

20 ml multidose amber glass vial of approximately 20 mm diameter, capped with grey bromobutyl rubber stopper and aluminium cap.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Unused product and waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Zoetis Ireland Limited
25/28 North Wall Quay
Dublin 1
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10438/083/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Renewal of the last authorisation: 12th December 2006

10 DATE OF REVISION OF THE TEXT

April 2015