Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Rimadyl 50 mg/ml solution for injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of product contains:	
Active substance	
Caprofen	50 mg
Excipients	
Ethanol	0.1 ml

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection.

A clear, pale straw coloured liquid.

4 CLINICAL PARTICULARS

4.1 Target Species

Young cattle (under 12 months of age) and equines.

4.2 Indications for use, specifying the target species

Rimadyl Solution is indicated as adjunctive therapy for the control of acute inflammation associated with respiratory disease in young cattle (under 12 months of age). The cause of the condition should be determined and treated with an appropriate antimicrobial.

In horses and ponies, it is indicated for analgesic and anti-inflammatory action in musculo-skeletal disorders and after surgery.

4.3 Contraindications

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 a 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.

4.4 Special warnings for each target species

None

4.5 Special precautions for use

Special precaution(s) for use in animals

Use in any animal less than 6 weeks of age 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.

In horses, concurrent administration of potential nephrotoxic drugs should be avoided.

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-infection. Avoid skin contact with the product. Wash off any splashes immediately.

4.6 Adverse reactions (frequency and seriousness)

Studies have suggested a transient nodule unassociated with heat or pain may form at the site of injection, although it is felt that this may be related to needle trauma rather than the product and has only been seen in a small number of animals.

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. During clinical studiess four different antibiotic classes were used, macrolides, tetracyclines, cephalosporins and potentiated penicillins without known interactions. The acute toxicity of carprofen in animals was not significantly affected in tests with 15 concomitantly administered drugs. These were acetylsalicylic acid, amphetamine, atropine, chlorpromazine, diazepam, diphenhydramine, ethyl alcohol, hydrochlorothiazide, imipramine, meperidine, propoxyphene, pentobarbital, sulfisoxazole, tetracycline and tolbutamide.

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

4.9 Amounts to be administered and administration route

For subcutaneous or intravenous administration to cattle. The recommended dose is 1.4 mg carprofen per kg bodyweight once, administered subcutaneously or intravenously.

In horses and ponies, administer by the intravenous route only. The recommended dosage is 0.7 mg/kg (1 ml/70 kg) bodyweight by intravenous injection as a single dose. This can be repeated after 24 hours, or followed by therapy with an oral formulation such as Rimadyl Granules for 4 or 9 days (giving a total treatment course of 5 or 10 days), according to the duration of clinical signs. After this, further use should follow another clinical evaluation.

4.10 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)

Animals may not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 21 days from last treatment.

Not for use in cattle producing milk for human consumption.

Horses: 4 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Non-steroidal antiinflammatory and antirheumatic products, propionic acid derivatives
ATCvet Code: QM01AE91

5.1 Pharmacodynamic properties

Carprofen is a member of the 2-arylpropionic acid group of non-steroidal anti-inflammatory drugs (NSAID's), and possesses anti-inflammatory, analgesic and antipyretic activity.

Carpofen, 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. Since prostaglandin inhibition is thought to underlie the principal toxic side-effects of NSAID's this lack of inhibition may explain the relative safety of carprofen. The precise mode of action is unclear.

5.2 Pharmacokinetic properties

Carprofen, in common with the other NSAIDs, exhibits age dependent pharmacokinetics, such that the half-life in calves with a mean bodyweight of 68kg is approximately 111 hours which is decreased to approximately half that value, (61 hours), for calves with a mean bodyweight of 90kg and beyond, (including adult cattle). Despite this, no difference has been seen in the duration of clinical efficacy in young cattle between 1 and 48 weeks of age.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol
Macrogol 400
Poloxamer 188
Ethanolamine
Water for injections

6.2 Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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

Do not store above 25°C. Protect from light.

6.5 Nature and composition of immediate packaging

50ml multidose amber glass (Type I) vials capped with a chlorobutyl rubber bung retained by an aluminium crimped seal.

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

Any unused product or waste materials 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 10438/081/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2007

10 DATE OF REVISION OF THE TEXT

12th October 2010

April 2014