IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007

(S.I. No. 786 of 2007)

VPA: **10019/063/001**
Case No: 7004839

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

Pfizer Healthcare Ireland

Trading as Pfizer Animal Health, **Ringaskiddy**, **Co. Cork**, **Ireland**

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Rimadyl Tablets 20 mg

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

The authorisation,unless revoked, shall continue in force from **25/08/2008** until **21/03/2011**.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: This authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Rimadyl Tablets 20 mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active Substance

Carprofen	20.0 mg

For a full list of excipients, see Section 6.1

3 PHARMACEUTICAL FORM

Tablet

White, circular flat tablets with a bevelled edge and a breakline on one side, embossed ’20 G CAR’ on the other side.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs.

4.2 Indications for use, specifying the target species

For analgesia e.g. in the management of post-operative pain, and reduction of chronic inflammation, for example in degenerative joint disease in the dog.

4.3 Contraindications

The elimination time of NSAIDs, 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 Tablets in the cat is contraindicated.

Do not use in dogs with known hypersensitivity to the active ingredient.

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.

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 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 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.

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
None.

4.6 Adverse reactions (frequency and seriousness)

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.

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

4.7 Use during pregnancy, lactation or lay

This product is not indicated for use in pregnant or lactating bitches.

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, hydrochlorothiazine, imipramine, meperidine, propoxyphene, pentobarbital, sulfisoxazole, tetracycline and tolbutamide.

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.

4.9 Amounts to be administered and administration route

For oral administration.

An initial dose of 2 to 4 mg carprofen per kg bodyweight per day is recommended to be given as a single 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 given as a single dose. To extend analgesic cover post-operatively, parenteral therapy with Rimadyl Injection may be followed with Rimadyl Tablets at 4mg/kg/day for up to 5 days.

Duration of treatment will be dependent upon the response seen, but the dog’s condition should be re-appraised by the veterinary surgeon after 14 days therapy.

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

Do not exceed the stated dose.

There is no specific antidote for carprofen overdosage 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 NSAID's 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 NSAIDs, lack of cyclo-oxygenase inhibition may explain the relative safety of carprofen. The precise mode of action of carprofen is not clear.

Carprofen has a long elimination half-life of around 18-21 hours (total carprofen) in both horses and ponies. As with other NSAIDs, carprofen accumulates in acute inflammatory exudates and is cleared more slowly from this fluid than from plasma.

The analgesic action has been proven to extend for approximately 24 hours. Analgesia in this species has been correlated with plasma concentrations in excess of 1.5 µg/ml. This level is achieved for around 12 hours in plasma, although mean exudate concentrations are maintained above this level for at least 24 hours.

Carprofen is a chiral drug with the S(+) enantiomer being more active than the R(-) enantiomer. There is no chiral inversion between the enantiomers *in-vivo*.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose
Maize Starch
Sodium Starch Glycolate
Colloidal Anhydrous Silica
Magnesium Stearate
Talc

6.2 Incompatibilities

None known.

6.3 Shelf-life

The shelf-life expiry date for this product shall not exceed 3 years from the date of its manufacture.

6.4 Special precautions for storage

Store in a dry place. Protect from light.

6.5 Nature and composition of immediate packaging

50 ml polypropylene 'Tracer' pack fitted with polyethylene tamper evident cap, or 45 ml polypropylene 'snap secure' tub with polyethylene cap containing 100 tablets.

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

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Pfizer Healthcare Ireland
Trading as: Pfizer Animal Health
Ringaskiddy
Co. Cork
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10019/063/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

22nd March 2006

10 DATE OF REVISION OF THE TEXT

25th August 2008