

IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10996/206/002**

Case No: 7004927

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:

Intervet Ireland Limited

Magna Drive, Magna Business Park, Dublin 24, 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:

Carprofen Intervet 50 mg tablets for dogs

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 **10/06/2009** until **06/12/2012**.

Signed on behalf of the Irish Medicines Board

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

Carprofen Intervet 50 mg tablets for dogs.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance(s):

Carprofen Intervet 50 mg tablets for dogs:

1 tablet contains:

Active substance:

50 mg Carprofen

Excipients:

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

White to slightly brown bone shape, one side scored tablet with little brown spots

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs.

4.2 Indications for use, specifying the target species

In the dog:

Reduction of inflammation and pain caused by musculo-skeletal disorders and degenerative joint disease. As a follow up to parenteral analgesia in the management of post-operative pain.

4.3 Contraindications

Do not use in cats.

Do not use in pregnant or lactating bitches.

Do not use in case of hypersensitivity to active substance or to any of the excipients.

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.

4.4 Special warnings for each target species

Refer to Sections 4.3 and 4.5

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, such dogs may require a reduced dosage and careful clinical management.

Avoid use in dehydrated, hypovolaemic or hypotensive dogs, 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 antimicrobial therapy should be instigated.

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.

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

In the event of accidental ingestion of the tablets, seek medical advice and show the doctor the package leaflet. Wash hands after handling the product.

4.6 Adverse reactions (frequency and seriousness)

Typical undesirable effects associated with NSAIDs, such as vomiting, soft faeces/diarrhea, faecal occult blood, loss of appetite and lethargy have been reported. These adverse reactions occur generally within the first treatment week and are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal.

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

If adverse reactions occur, use of the product should be stopped and the advice of a veterinarian should be sought.

4.7 Use during pregnancy, lactation or lay

Studies in laboratory species (rat and rabbit) have shown evidence of foetotoxic effects of carprofen at doses close to the therapeutic dose. The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Do not use in pregnant or lactating bitches.

4.8 Interaction with other medicinal products and other forms of interaction

Carprofen must not be administered with glucocorticoids.

Refer also to section 4.5.

4.9 Amounts to be administered and administration route

For oral administration.

2 to 4 mg carprofen per kg bodyweight per day.

An initial dose of 4 mg carprofen per kg bodyweight per day given as a single daily dose or in two equally divided doses may, subject to clinical response, be reduced after 7 days to 2 mg carprofen/kg bodyweight/day given as a single dose.

Duration of treatment will be dependant upon the response seen. Long term treatment should be under regular veterinary supervision.

To extend analgesic and anti-inflammatory cover post-operatively, parenteral preoperative treatment may be followed with Carprofen Intervet tablets at 4mg/kg/day for up to 5 days.

Do not exceed the stated dose.

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 NSAIDs, should be applied.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Non-steroidal anti-inflammatory drug. ATC Vet Code: QM01AE91.

5.1 Pharmacodynamic 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 is a chiral drug with the S(+) enantiomer being more active than the R(-) enantiomer. 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. The precise mode of action of carprofen is not clear.

5.2 Pharmacokinetic properties

After oral administration, carprofen is well absorbed in the dogs. Following the administration of the 50 mg product in dogs, a mean C_{max} (maximum concentration in plasma) of 31.7 µg carprofen/ml was achieved at approximately 1 hour. The mean half-life was approximately 14 hours. The analgesic effect from each dose persists for at least 12 hours. Carprofen has a small volume of distribution and a low systemic clearance. It is highly bound to plasma protein. Carprofen is metabolised in the liver by conjugation and oxidation. The excretion of the glucuronide conjugate is mainly faecal after biliary excretion.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Artificial beef flavour (containing hydrolyzed soybean protein, hydrogenated soybean oil, pork liver)
Calcium hydrogen phosphate, anhydrous
Microcrystalline cellulose
Colloidal anhydrous silica
Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf-life

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

6.4 Special precautions for storage

The product does not require any special storage conditions within EU countries

6.5 Nature and composition of immediate packaging

Square white high-density polyethylene bottle fitted with child resistant polypropylene closure.
Several presentations of Carprofen Intervet tablets are available: the bottles may contain 28 or 84 Carprofen Intervet 50mg tablets.
Not all pack sizes may be marketed.

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

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

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Ltd
Magna Drive
Magna Business Park
Citywest Road
Dublin

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/206/002

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

7th December 2007

10 DATE OF REVISION OF THE TEXT

10th June 2009