Elanco UK AH Limited

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Galliprant tablets for dogs

Species: Dogs

Therapeutic indication:Pharmaceuticals: Anti-inflammatory preparations: Oral: Other NSAIDs, **Pharmaceuticals:** Locomotor (including navicular and osteoarthritis), **Pharmaceuticals: Neurological preparations:** Analgesics

Active ingredient: Grapiprant

Product: Galliprant tablets for dogs

Product index: Galliprant tablets for dogs

Incorporating: Galliprant 20 mg tablets for dogs

Galliprant 60 mg tablets for dogs

Galliprant 100 mg tablets for dogs

Qualitative and quantitative composition

Each tablet contains:

Active substance:

Grapiprant 20 mg

Grapiprant 60 mg

Grapiprant 100 mg

For the full list of excipients, see section Pharmaceutical Particulars

Pharmaceutical form

20 mg tablet: A brown speckled, biconvex oval tablet with a score on one face separating the debossed number ‘20’ on one half and the letters ‘MG’ on the other half; the letter ‘G’ is debossed on the other face. The tablet can be divided into equal halves.

60 mg tablet: A brown speckled, biconvex oval tablet with a score on one face separating the debossed number '60' on one half and the letters 'MG' on the other half; the letter 'G' is debossed on the other face. The tablet can be divided into equal halves.

100 mg tablet: A brown speckled, biconvex oval tablet with the debossed number '100' on one half and the letters 'MG' on the other half; the letter 'G' is debossed on the other face.

Clinical particulars

Target species

Dogs.

Indications for use, specifying the target species

For the treatment of pain associated with mild to moderate osteoarthritis in dogs.

Contraindications

Do not use in case of hypersensitivity to the active substance or any of the excipients. Do not use in pregnant, lactating or breeding animals, see section below.

Special warnings for each target species

The majority of clinical cases assessed in the clinical field studies suffered from mild to moderate osteoarthritis based on the veterinary assessment. To achieve a substantiated response to treatment, use the veterinary medicinal product only in mild and moderate cases of osteoarthritis.

From the two clinical field studies, the overall success rates based on CBPI (Canine Brief Pain Inventory, as completed by the owner) at 28 days after the start of the treatment, were 51.3% (120/235) for Galliprant and 35.5% (82/231) for the placebo group. This difference in favour of Galliprant was statistically significant (p-value= 0.0008).

A clinical response to treatment is usually seen within 7 days. If no clinical improvement is apparent after 14 days, treatment with Galliprant should be iscontinued and different treatment options should be explored in consultation with the veterinarian.

Special precautions for use

Special precautions for use in animals

Grapiprant is a methylbenzenesulfonamide. It is not known whether dogs with a history of hypersensitivity to sulphonamides will exhibit hypersensitivity to grapiprant. If signs of sulphonamide hypersensitivity occur, treatment should be discontinued.

Use with caution in dogs suffering from pre-existing liver, cardiovascular or renal dysfunctions or from gastrointestinal disease.

The concurrent use of grapiprant with other anti-inflammatory agents has not been studied and should be avoided.

The safety of the veterinary medicinal product has not been established in dogs under 9 months of age and in dogs weighing less than 3.6 kg.

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

Wash hands after handling of the veterinary medicinal product.

In case of accidental ingestion by children, mild and reversible gastrointestinal signs and nausea may be observed. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment

Not applicable

Adverse reactions (frequency and seriousness)

Target species: Dogs

Very common (>1 animal / 10 animals treated):	Vomiting
Common (1 to 10 animals / 100 animals treated):	Loose stool, Diarrhoea Inappetance
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Haematemesis, Haemorrhagic diarrhoea Pancreatitis Elevated blood urea nitrogen (BUN), Elevated creatini Hypoalbuminaemia1, Hypoproteinaemia1

1These signs were not associated with any clinically significant observations or events.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See section 'Contact details' of the package insert.

Use during pregnancy, lactation or lay

Do not use in pregnant, lactating or breeding animals as the safety of grapiprant has not been established during pregnancy and lactation or in dogs used for breeding.

Interaction with other medicinal products and other forms of interaction

Prior treatment with other anti-inflammatory substances may result in additional or increased severity of adverse effects and accordingly a treatment-free period with such veterinary medicinal

products should be observed before the commencement of treatment with this veterinary medicinal product. The treatment-free period should take into account the pharmacokinetic properties of the products used previously.

The concomitant use of protein-bound veterinary medicinal products with grapiprant has not been studied. Commonly used protein-bound veterinary medicinal products include cardiac, anticonvulsant and behavioural medications.

Veterinary medicinal product compatability should be monitored in animals requiring adjunctive therapy.

Amounts to be administered and administration route

For oral use.

Administer this veterinary medicinal product on an empty stomach (e.g. in the morning) and at least one hour before the next meal, once daily at a target dose of 2 mg per kg body weight (bw).

Duration of treatment will depend on the response observed to treatment. As field studies were limited to 28 days, longer-term treatment should be considered carefully and regular monitoring undertaken by the veterinarian.

Since clinical signs of canine osteoarthritis wax-and-wane, intermittent treatment may be beneficial in some dogs.

The following number of tablets should be given once daily:

Body weight (kg)	20 mg tablet	60 mg tablet	100 mg tablet	D
3.6 - 6.8	0.5			1
6.9 - 13.6	1			1
13.7 - 20.4		0.5		1
20.5 - 34.0		1		1
34.1 - 68.0			1	1
68.1 - 100.0			2	2

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

In healthy dogs treated with grapiprant for 9 consecutive months, mild and transient soft-formed or mucous faeces, occasionally bloody, and vomiting were observed at daily overdoses of

approximately 2.5x and 15x the recommended dose. Grapiprant did not produce any signs of kidney or liver toxicity at daily overdoses of up to 15x the recommended dose.

In case of overdose, symptomatic treatment should be initiated.

Withdrawal period(s)

Not applicable.

Pharmacological particulars

Pharmacotherapeutic group: Other anti-inflammatory and antirheumatic agents, non-steroids

ATCvet code: QM01AX92

Pharmacodynamic properties

Grapiprant is a non-steroidal, non-cyclooxygenase inhibiting anti-inflammatory drug in the piprant class. Grapiprant is a selective antagonist of the EP4 receptor, a key prostaglandin E2 receptor that predominantly mediates prostaglandin E2-elicited nociception. The specific effects of the binding of prostaglandin E2 to the EP4 receptor include vasodilation, increased vascular permeability, angiogenesis and production of pro-inflammatory mediators. The EP4 receptor is important in mediating pain and inflammation as it is the primary mediator of the prostaglandin E2-elicited sensitization of sensory neurons and prostaglandin E2-elicited inflammation.

Pharmacokinetic particulars

Absorption

Grapiprant is readily and rapidly absorbed from the gastrointestinal tract in dogs. After a single oral dose of 2 mg grapiprant/kg, Cmax and AUC values of 1.21 µg/ml and 2.71 µg.h/ml were reached in the fasted state. Maximum grapiprant concentrations are observed in serum within one hour of dosing in the fasted state. Intake of the tablet with food reduces the oral bioavailability, i.e. the oral bioavailability of grapiprant when taken in the fasted state was 89% and when taken with food it was 33%, with mean Cmax and AUC grapiprant values reduced 4-fold and 2-fold, respectively. Grapiprant does not accumulate in the dog after repeated administration. No gender related differences in absorption are observed.

Distribution

In vitro protein binding of grapiprant indicates that grapiprant is primarily bound to dog serum albumin. The mean percentage of unbound grapiprant was 4.35% and 5.01% at a grapiprant concentration of 200 ng/ml and 1000 ng/ml.

Biotransformation

Grapiprant is primarily bound to serum proteins. In dogs, grapiprant is a major excretion product in bile, faeces and urine. Four metabolites are identified and the metabolic pathways include N-deamination to form the major metabolite in faeces (7.2%) and urine (3.4%). Two hydroxylated

metabolites and one N-oxidated metabolite are also recovered in bile, faeces and/or urine. The pharmacological activity of the metabolites is not known.

Elimination

Grapiprant is primarily excreted via faeces. Approximately 70-80% of the administered dose is excreted within 48-72 h with the majority of the dose excreted unchanged. Faecal excretion accounted for roughly 65% of the dose whereas approximately 20% of the dose was excreted through urine.

The elimination half-life of grapiprant is approximately 4.6 to 5.67 hours.

Pharmaceutical particulars

List of excipients

Pork liver powder
Lactose monohydrate
Sodium starch glycolate Type A
Sodium laurilsulfate
Copovidone
Cellulose, microcrystalline
Magnesium stearate
Silica, colloidal anhydrous

Major incompatibilities

Not applicable.

Shelf life

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

Shelf life after first opening the immediate packaging: 3 months.

Any remaining whole and half tablets should be discarded after 3 months following first opening.

Special precautions for storage

Do not store above 30 °C.

Any half tablets should be stored in the bottle.

In order to avoid any accidental ingestion, store tablets out of reach of animals.

Nature and composition of immediate packaging

Induction sealed, white, round high density polyethylene (HDPE) bottles with a threaded child-resistant cap with rayon coil.

Pack sizes of 7 and 30 tablets per bottle. One bottle per cardboard box.

Not all pack sizes may be marketed.

Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.

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

Marketing Authorisation Holder (if different from distributor)

Elanco GmbH
Heinz-Lohmann-Str. 4
27472 Cuxhaven
Germany

Marketing Authorisation Number

Galliprant 20 mg tablets for dogs: Vm (GB) 52127/5017

Galliprant 60 mg tablets for dogs: Vm (GB) 52127/5018

Galliprant 100 mg tablets for dogs: Vm (GB) 52127/5016

Galliprant (Northern Ireland) EU/2/17/221/001 - 006

Significant changes

Date of the first authorisation or date of renewal

Date of first authorisation: 09/01/2018

Date of revision of the text

August 2023

Any other information

Veterinary medicinal product subject to prescription.

Legal category

Legal category:POM-V

GTIN

GTIN description:GALLIPRANT 20MG x 7TAB BOTL

GTIN:05014602808280

GTIN description:GALLIPRANT 20MG x 30TAB BOTL

GTIN:05014602808297

NOAH Compendium

GTIN description:GALLIPRANT 60MG x 7TAB BOTL

GTIN:05014602808303

GTIN description:GALLIPRANT 60MG x 30TAB BOTL

GTIN:05014602808310

GTIN description:GALLIPRANT 100MG x 7TAB BOTL

GTIN:05014602808327

GTIN description:GALLIPRANT 100MG x 30TAB BOTL

GTIN:05014602808334