PACKAGE LEAFLET:

Galliprant 20 mg tablets for dogs

Galliprant 60 mg tablets for dogs

Galliprant 100 mg tablets for dogs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Elanco GmbH, Heinz-Lohmann Strasse 4, Groden, 27472 Cuxhaven
Germany
Manufacturer responsible for batch release:
Elanco France S.A.S., 26 Rue de la Chapelle, 68330 Huningue, France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Galliprant 20 mg tablets for dogs

Galliprant 60 mg tablets for dogs

Galliprant 100 mg tablets for dogs
grapiprant

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

One tablet contains:
Active substance:

Grapiprant	20 mg
Grapiprant	60 mg
Grapiprant	100 mg

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.

4. INDICATION(S)

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

5. 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.

6. ADVERSE REACTIONS

Vomiting was observed very commonly in clinical studies. Soft-formed faeces, diarrhoea and inappetence were commonly observed in clinical studies. These signs were generally transient.

Elevated liver enzymes, elevated BUN, elevated creatinine, haematemesis and haemorrhagic diarrhoea have been reported very rarely following use post authorisation.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

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	Dose range (mg/kg bw)
3.6-6.8	0.5			1.5-2.7
6.9-13.6	1			1.5-2.9
13.7-20.4		0.5		1.5-2.2
20.5-34.0		1		1.8-2.9
34.1-68.0			1	1.5-2.9
68.1-100.0			2	2.0-2.9

9. ADVICE ON CORRECT ADMINISTRATION

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 drugs 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.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
In order to avoid any accidental ingestion, store tablets out of reach of animals.
Do not store above 30 °C.
Any half tablets should be stored in the bottle.

Do not use this veterinary medicinal product after the expiry date, which is stated on the carton and bottle after EXP. The expiry date refers to the last day of that month.
Shelf-life after first opening of the bottle: 3 months. Any remaining whole and half tablets should be discarded after 3 months following first opening of the bottle.

12. SPECIAL WARNING(S)

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 discontinued and different treatment options should be explored in consultation with the veterinarian.
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.
Mild decreases in serum albumin and total protein, most often within the reference range, have been observed in dogs treated with grapiprant but were not associated with any clinically significant observations or events.
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.

Interaction with other medicinal products and other forms of interaction:
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.
Drug compatibility should be monitored in animals requiring adjunctive therapy.
Pregnancy:
Do not use in pregnant animals as the safety of grapiprant has not been established during pregnancy.
Lactation:
Do not use lactating animals as the safety of grapiprant has not been established during lactation.
Fertility:
Do not use in breeding animals as the safety of grapiprant has not been established or in dogs used for breeding.
Overdose (symptoms, emergency procedures, antidotes):
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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED November 2021

15. OTHER INFORMATION

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 E_2 receptor that predominantly mediates prostaglandin E_2-elicited nociception. The specific effects of the binding of prostaglandin E_2 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 E_2-elicited sensitization of sensory neurons and prostaglandin E_2-elicited inflammation.
Grapiprant is readily and rapidly absorbed from the gastrointestinal tract in dogs.
Grapiprant is mainly excreted via faeces.

The veterinary medicinal product is available in the following pack sizes:
One white HDPE bottle with a child-resistant cap containing 7 or 30 tablets (20 mg, 60 mg or 100 mg tablets). Not all pack sizes may be marketed.