ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box (50 ml and 120 ml bottles)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Galliprant 60 mg tablets

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains 60 mg grapiprant

3. PACKAGE SIZE

7 tablets
30 tablets

4. TARGET SPECIES

Dogs

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use by:….

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 30 °C.
Any half tablets should be stored in the bottle.
Store out of reach of animals.
Keep the bottle in the outer carton.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Elanco GmbH
Heinz-Lohmann Strasse 4
Groden
27472 Cuxhaven
Germany

14. MARKETING AUTHORISATION NUMBER

Vm 52127/5018

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V
To be supplied only on veterinary prescription.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle (50 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Galliprant

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

60 mg grapiprant

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use by: …

5. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

7 tablets
30 tablets

6. ROUTE(S) OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIOD

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Galliprant 20 mg tablets for dogs
Galliprant 60 mg tablets for dogs
Galliprant 100 mg tablets for dogs

2. COMPOSITION

Each tablet contains:

Active substance:

Grapiprant	20 mg
Grapiprant	60 mg
Grapiprant	100 mg

Galliprant 20 mg tablets: 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.

Galliprant 60 mg tablets: 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.

Galliprant 100 mg tablets: 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.

3. TARGET SPECIES

Dogs

4. INDICATIONS FOR USE

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

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in pregnant, lactating or breeding animals.

6. SPECIAL WARNING(S)

Special warnings:

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 safe use in the target species:

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.

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.

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

Overdose:

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.

7. ADVERSE EVENTS

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 Pancreatic inflammation Elevated blood urea nitrogen (BUN), Elevated creatinine, Elevated liver enzymes, Hypoalbuminaemia[1], Hypoproteinaemia[1]

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

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

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 (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	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 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.

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 PRECAUTIONS FOR DISPOSAL

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.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 52127/5018

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.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2023

16. CONTACT DETAILS

Marketing authorisation holder and contact details to report suspected adverse reactions:

Elanco GmbH
Heinz-Lohmann Strasse 4
Groden
27472 Cuxhaven
Germany

Tel: +44 3308221732

PV.GBR@elancoah.com

Manufacturer responsible for batch release:

Elanco France S.A.S.
26 Rue de la Chapelle
68330 Huningue
France

17. 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.

Approved 22 August 2023