ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

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. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:

Grapiprant	20 mg
Grapiprant	60 mg
Grapiprant	100 mg

Excipients:

Qualitative composition of excipients and other constituents
Pork liver powder
Lactose monohydrate
Sodium starch glycolate Type A
Sodium laurilsulfate
Copovidone
Cellulose, microcrystalline
Magnesium stearate
Silica, colloidal anhydrous

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. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

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

3.3 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. See section 3.7.

3.4 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.

3.5 Special precautions for use

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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Target species: Dogs

Very common (>1 animal / 10 animals treated):	Vomiting
Common	Loose stool, Diarrhoea

(1 to 10 animals / 100 animals treated):	Inappetance
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Haematemesis, Haemorrhagic diarrhoea Pancreatitis 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 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 also section `Contact details´ of the package leaflet.

3.7 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.

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

3.9 Administration routes and dosage

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

3.10 Symptoms of overdose (and where applicable, emergency procedures and 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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code

QM01AX92

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

Absorption
Grapiprant is readily and rapidly absorbed from the gastrointestinal tract in dogs. After a single oral dose of 2 mg grapiprant/kg, C_{max} 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 C_{max} 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 1 000 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 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.

5.3 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.

5.4 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.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco GmbH

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/17/221/001-006

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 09/01/2018

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None.

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 20 mg tablets
Galliprant 60 mg tablets
Galliprant 100 mg tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains 20 mg grapiprant.
Each tablet contains 60 mg grapiprant.
Each tablet contains 100 mg grapiprant.

3. PACKAGE SIZE

7 tablets
30 tablets

4. TARGET SPECIES

Dogs

5. INDICATIONS

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.

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 OF THE MARKETING AUTHORISATION HOLDER

Elanco logo

14. MARKETING AUTHORISATION NUMBERS

EU/2/17/221/001 (20 mg, 7 tablets, 50 ml bottle)
EU/2/17/221/002 (20 mg, 30 tablets, 50 ml bottle)
EU/2/17/221/003 (60 mg, 7 tablets, 50 ml bottle)
EU/2/17/221/004 (60 mg, 30 tablets, 50 ml bottle)
EU/2/17/221/005 (100 mg, 7 tablets, 50 ml bottle)
EU/2/17/221/006 (100 mg, 30 tablets, 120 ml bottle)

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle (120 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Galliprant 100 mg tablets

2. STATEMENT OF ACTIVE SUBSTANCES

100 mg grapiprant

3. TARGET SPECIES

Dogs

4. ROUTES OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use by:

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco logo

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle (50 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Galliprant

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

20 mg grapiprant
60 mg grapiprant
100 mg grapiprant

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use by:

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 warnings

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: {national system details}.

8. Dosage for each species, routes 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 periods

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 or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/17/221/001-006

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 revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
Elanco GmbH, Heinz-Lohmann-Str. 4, 27472 Cuxhaven, Germany

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Tel: +44 3308221732
PV.XXI@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.