

GALLIPRANT- grapiprant tablet
Elanco US Inc.

Galliprant®

(grapiprant tablets)

For oral use in dogs only

Flavored tablets

A prostaglandin E₂ (PGE₂) EP4 receptor antagonist; a non-cyclooxygenase inhibiting, non-steroidal, anti-inflammatory drug.

Information for Dog Owners

GALLIPRANT is indicated for the control of pain and inflammation due to osteoarthritis.

This sheet contains important information about GALLIPRANT. You should read this information before starting your dog on GALLIPRANT and review it each time the prescription is refilled. This information provides a summary and does not take the place of the instructions from your veterinarian. Talk to your veterinarian if you do not understand any of this information or you want more information about GALLIPRANT.

GALLIPRANT is a prostaglandin E₂ (PGE₂) EP4 receptor antagonist; a non-cyclooxygenase (COX) inhibiting, non-steroidal, antiinflammatory drug (NSAID). As an antiinflammatory, GALLIPRANT is indicated for the control of pain and inflammation associated with osteoarthritis in dogs.

Control of pain and inflammation may vary from dog to dog. Consult your veterinarian if your dog appears to be uncomfortable. GALLIPRANT may need to be given for an extended period of time. Use the lowest dose to provide adequate pain control. Always consult with your veterinarian before altering the dose.

It is important to periodically discuss your dog's response to GALLIPRANT with your veterinarian. Your veterinarian will discuss appropriate monitoring while your dog is on GALLIPRANT.

The most common side effects associated with GALLIPRANT include vomiting, soft, mucoid stools, diarrhea and decreased appetite. You should contact your veterinarian if your dog's appetite decreases or stools become abnormal.

Dogs should not take GALLIPRANT if:

- Your dog is presently taking aspirin, other NSAIDs, or corticosteroids (unless directed by your veterinarian).
- Your dog has had an allergic reaction (such as hives, facial swelling, or itchy skin) to GALLIPRANT. Inform your veterinarian if your dog has had an allergic reaction to other anti-inflammatory drugs.
- Your dog is under 8 pounds in body weight.

GALLIPRANT should only be given to dogs. Do not use in cats. GALLIPRANT should not be given with other non-steroidal anti-inflammatory drugs (NSAIDs) or corticosteroids (for example, aspirin, carprofen, meloxicam and prednisone).

Not for use in humans. Keep this and all medications out of reach of children and pets. Consult a physician in case of accidental ingestion by humans. Store GALLIPRANT out of reach of dogs and other pets in a secured location in order to prevent accidental ingestion or overdose. Tell your veterinarian about:

- Any side effects your dog has experienced from GALLIPRANT or other NSAIDs.

- Any digestive issues (bloody, mucoid stool, vomiting or diarrhea, or decreased appetite) your dog has.
- Any other medical problems or allergies that your dog has had.
- All medications that you are giving your dog or plan to give your dog, including those you can get without a prescription and any dietary supplements.
- If you plan to breed your dog, or if your dog is pregnant or nursing.

If you have additional questions about possible side effects while your dog is on GALLIPRANT, talk with your veterinarian or call 1-888-545-5973.

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February 2018

PA100845X

ARATANA THERAPEUTICS®

Elanco™

GALLIPRANT® (grapiprant tablets)

For oral use in dogs only

20 mg, 60 mg and 100 mg flavored tablets

A prostaglandin E₂ (PGE₂) EP4 receptor antagonist; a non-cyclooxygenase inhibiting, non-steroidal anti-inflammatory drug

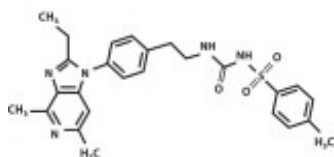
Caution:

Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

Description:

GALLIPRANT (grapiprant tablets) is a prostaglandin E₂ (PGE₂) EP4 receptor antagonist; a non-cyclooxygenase (COX) inhibiting, non-steroidal anti-inflammatory drug (NSAID) in the piprant class. GALLIPRANT is a flavored, oval, biconvex, beige to brown in color, scored tablet debossed with a “G” that contains grapiprant and desiccated pork liver as the flavoring agent.

The molecular weight of grapiprant is 491.61 Daltons. The empirical formula is C₂₆H₂₉N₅O₃S. Grapiprant is N-[[[2-[4-(2-Ethyl-4,6-dimethyl-1H-imidazo[4,5-c]pyridin-1-yl)phenyl]ethyl]amino]carbonyl]4-methylbenzenesulfonamide. The structural formula is:



Indication:

GALLIPRANT (grapiprant tablets) is indicated for the control of pain and inflammation associated with osteoarthritis in dogs.

Dosage and Administration:

Always provide “Information for Dog Owners” Sheet with prescription.

Use the lowest effective dose for the shortest duration consistent with individual response.

The dose of GALLIPRANT (grapiprant tablets) is 0.9 mg/lb (2 mg/kg) once daily.

GALLIPRANT tablets are scored and dosage should be calculated in half tablet increments. Dogs less than 8 lbs (3.6 kgs) cannot be accurately dosed.

Dosing Chart

Dose	Weight in pounds	Weight in kilograms	20 mg tablet	60 mg tablet	100 mg tablet
0.9 mg/lb (2 mg/kg) once daily	8-15	3.6-6.8	0.5		
	15.1-30	6.9-13.6	1		
	30.1-45	13.7-20.4		0.5	
	45.1-75	20.5-34		1	
	75.1-150	34.1-68			1
	150.1-220	68.1-100			2

To break the tablets in half, hold the tablet between the thumb and index finger of each hand on either side of the score line, with the score line facing downward. Separate into two halves by breaking the tablet down toward the score line.

Contraindications:

GALLIPRANT should not be used in dogs that have a hypersensitivity to grapiprant.

Warnings:

Not for use in humans. Keep this and all medications out of reach of children and pets. Consult a physician in case of accidental ingestion by humans. **For use in dogs only.** Store GALLIPRANT out of reach of dogs and other pets in a secured location in order to prevent accidental ingestion or overdose.

Precautions:

The safe use of GALLIPRANT has not been evaluated in dogs younger than 9 months of age and less than 8 lbs (3.6 kg), dogs used for breeding, or in pregnant or lactating dogs.

Adverse reactions in dogs receiving GALLIPRANT may include vomiting, diarrhea, decreased appetite, mucoid, watery or bloody stools, and decreases in serum albumin and total protein.

If GALLIPRANT is used long term appropriate monitoring is recommended.

Concurrent use with other anti-inflammatory drugs has not been studied. Concomitant use of GALLIPRANT with other anti-inflammatory drugs, such as COX-inhibiting NSAIDs or corticosteroids, should be avoided. If additional pain medication is needed after a daily dose of GALLIPRANT, a non-NSAID/non-corticosteroid class of analgesic may be necessary.

The concomitant use of protein-bound drugs with GALLIPRANT has not been studied. Commonly used protein-bound drugs include cardiac, anticonvulsant and behavioral medications.

Drug compatibility should be monitored in patients requiring adjunctive therapy. Consider appropriate washout times when switching from one anti-inflammatory to another or when switching from corticosteroids or COX-inhibiting NSAIDs to GALLIPRANT use.

The use of GALLIPRANT in dogs with cardiac disease has not been studied.

It is not known whether dogs with a history of hypersensitivity to sulfonamide drugs will exhibit hypersensitivity to GALLIPRANT. GALLIPRANT is a methylbenzenesulfonamide.

Adverse Reactions:

In a controlled field study, 285 dogs were evaluated for safety when given either GALLIPRANT or a vehicle control (tablet minus grapiprant) at a dose of 2 mg/kg (0.9 mg/lb) once daily for 28 days.

GALLIPRANT-treated dogs ranged in age from 2 yrs to 16.75 years. The following adverse reactions were observed:

Table 1. Adverse reactions reported in the field study.

Adverse reaction*	GALLIPRANT (grapiprant tablets) N = 141	Vehicle control (tablets minus grapiprant) N = 144
Vomiting	24	9
Diarrhea, soft stool	17	13
Anorexia, inappetence	9	7
Lethargy	6	2
Buccal ulcer	1	0
Immune mediated hemolytic anemia	1	0

*Dogs may have experienced more than one type or occurrence during the study.

GALLIPRANT was used safely during the field studies with other concurrent therapies, including antibiotics, parasiticides and vaccinations.

To report suspected adverse drug events and/or to obtain a copy of the Safety Data Sheet (SDS) or for technical assistance, call 1-888-545-5973.

For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at <http://www.fda.gov/AnimalVeterinary/SafetyHealth>

Information for Dog Owners:

Owners should be advised of the potential for adverse reactions and be informed of the clinical signs associated with drug intolerance. Adverse reactions may include vomiting, diarrhea, decreased appetite, and decreasing albumin and total protein. Appetite and stools should be monitored and owners should be advised to consult with their veterinarian if appetite decreases or stools become abnormal.

Clinical Pharmacology:

Grapiprant is a prostaglandin E₂ (PGE₂) EP₄ receptor antagonist; a non-cyclooxygenase inhibiting, non-steroidal, anti-inflammatory drug. Grapiprant has a canine EP₄ receptor binding affinity (K_i) of 24 nM.

Prostaglandins have a wide variety of physiologic effects. Prostaglandin

E₂ (PGE₂) is a prostanoid that exerts its effects via four receptors, EP₁, EP₂, EP₃, and EP₄. PGE₂ is involved in mediating inflammatory pain, vasodilation, increasing vascular permeability; as well as gastrointestinal homeostasis, renal function and reproductive functions. The EP₄ receptor is important in mediating pain and inflammation as it is the primary mediator of the PGE₂-elicited sensitization of sensory neurons¹ and PGE₂-elicited inflammation.² Grapiprant blocks PGE₂-elicited pain and inflammation by antagonizing the EP₄ receptor.

The EP4 receptor, along with the EP1, EP2 and EP3 receptors, is involved in PGE₂ mediated effects on gastrointestinal homeostasis and renal function. PGE₂ effects mediated solely by the EP4 receptor are stimulation of mucus secretion in the stomach and large intestine, stimulation of acid secretion in the stomach, inhibition of small intestine motility and inhibition of cytokine expression in the large intestine.³

While PGE₂ gastroprotective action is mediated by EP1, the healing-promoting action of PGE₂ in the stomach is mediated by the EP4 receptor.⁴ In the kidney, the PGE₂ antinatriuretic effect is mediated by the EP4 receptor.⁵

EP4 receptors are abundantly expressed in the heart of dogs,⁶ the clinical relevance of which is unknown. The EP4 receptor is not involved in generation of pyrexia.

Grapiprant is not a potential inhibitor of CYP1A2, CYP2C9, CYP2C19, CYP2D6, and CYP3A4 mediated metabolism pathways. Grapiprant is a substrate of P-glycoprotein transport. *In vitro* metabolism with dog liver microsomes identified two oxidative metabolites, M3 (hydroxyl) and M5 (N-dealkylation).

The pharmacokinetic characterization of grapiprant following oral administration of GALLIPRANT tablets to healthy Beagles is provided in the table below.

Table 2. Mean (±SD) Plasma Pharmacokinetic Parameters for Grapiprant in Beagles after single oral dose of GALLIPRANT tablet formulation

Study	Study 1 ¹	Study 1 ¹	Study 2 ²	Study 2 ²
PK Parameter	2 mg/kg (n = 10) (Fasted)	2 mg/kg (n = 10) (Fed)	6 mg/kg (n = 8) (Fasted)	50 mg/kg (n = 8) (Fasted)
T _{max} ³ (hr)	1.0 (0.5 – 1.03)	1.0 (0.5 – 8.07)	1.0 (1.0 – 2.0)	2.0 (1.0 – 4.0)
C _{max} (ng/mL)	1210 (341)	278 (179)	5720 (3220)	98500 (13100)
AUC(0-inf) (ng*hr/mL)	2790 (982)	1200 (523)	17800 (5520)	414000 (73700)
T _{1/2} (hr)	4.60 (4.19)	5.67 (3.27)	5.01 (1.95)	5.21 (1.66)
Fed/Fasted Relative Bioavailability Geometric Mean Ratio of AUC (90% Confidence Limits)	0.37 (0.28 – 0.46)		NA	

¹Study 1 was a food effect determination study.

²Study 2 was a PK bridging study conducted using 60 mg GALLIPRANT tablets at 6 mg/kg dose and 5 X 100 mg GALLIPRANT tablets at 50 mg/kg dose.

³Median (Range)

Grapiprant is absorbed rapidly following an oral dose of the GALLIPRANT; with C_{max} values achieved within approximately 2 hr post-dose (T_{max}). Intake of the tablet with food significantly reduces the oral bioavailability, with mean C_{max} and AUC grapiprant values reduced 4-fold and 2-fold, respectively. The systemic grapiprant exposure increases in a greater than dose proportional manner. The mean terminal elimination half-life (T_{1/2}) ranges between 4.60 to 5.67 hr. Following once daily dosing, negligible drug accumulation in the blood is anticipated. Following an oral dose of radiolabeled grapiprant to dogs, the majority of the dose was excreted within the first 72 hr (84%) and

approximately 88.7% of the dose was excreted in 192 hr. In a bile duct cannulated dog study, approximately 55.6%, 15.1% and 19.1% of the dose was excreted in bile, urine and feces, respectively, suggesting the high oral bioavailability of grapiprant in dogs (> 70%). Four metabolites were identified; two hydroxylated metabolites, one N-deamination metabolite (major metabolite urine (3.4%) and feces (7.2%)) and one N-oxidation metabolite. Metabolite activity is not known. Plasma protein binding of grapiprant was ~95%.

Effectiveness:

Two hundred and eighty five (285) client-owned dogs were enrolled in the study and evaluated for field safety. GALLIPRANT-treated dogs ranging in age from 2 to 16.75 years and weighing between 4.1 and 59.6 kgs (9 – 131 lbs) with radiographic and clinical signs of osteoarthritis were enrolled in a placebo-controlled, masked field study. Dogs had a 7-day washout from NSAID or other current OA therapy. Two hundred and sixty two (262) of the 285 dogs were included in the effectiveness evaluation. Dogs were assessed for improvements in pain and function by the owners using the Canine Brief Pain Inventory (CBPI) scoring system.⁷ A statistically significant difference in the proportion of treatment successes in the GALLIPRANT group (63/131 or 48.1%) was observed compared to the vehicle control group (41/131 or 31.3%). GALLIPRANT demonstrated statistically significant differences in owner assessed pain and function. The results of the field study demonstrate that GALLIPRANT, administered at 2 mg/kg (0.9 mg/pound) once daily for 28 days, was effective for the control of pain and inflammation associated with osteoarthritis.

Animal Safety:

In a 9-month toxicity study, grapiprant in a methylcellulose suspension was administered by oral gavage once daily to healthy Beagles at doses of 1, 6, and 50 mg/kg/day. Based on a relative bioavailability study comparing grapiprant in methylcellulose suspension to GALLIPRANT tablets, the corresponding equivalent doses were 0.75 mg/kg (0.12X – 0.25X), 4.44 mg/kg (0.72X – 1.48X) and 30.47 mg/kg (4.88X – 10.16X) of the GALLIPRANT tablets. Four animals/sex were used in each dose group and 2 additional animals/sex were used in the 50 mg/kg dose group to evaluate recovery after drug cessation. Vomiting and soft-formed or mucus stool were observed in all groups, including controls, with higher incidence in grapiprant-treated dogs. Decreases in serum albumin and total protein were seen with increasing doses of grapiprant. Hypoalbuminemia and hypoproteinemia were reversible when treatment was discontinued. Three treated dogs and one control dog had elevated alkaline phosphatase values. One animal in the 50 mg/kg group (equivalent to 30.47 mg/kg of tablet formulation) had mild regeneration of the mucosal epithelium of the ileum.

In a field study conducted in 366 client-owned dogs to evaluate

GALLIPRANT at doses of 2 mg/kg once daily, 5 mg/kg once daily, 4 mg/kg twice daily, or placebo twice daily, the most common adverse reactions related to treatment were diarrhea, vomiting and inappetence. Changes in clinical pathology included concurrent elevations of alkaline phosphatase and alanine aminotransferase values on Day 28, and dose-dependent decreases in total protein values. There was no clinical impact related to these clinical pathology changes.

Storage Conditions:

Store at or below 86° F (30° C)

How Supplied:

20 mg, 60 mg and 100 mg flavored tablets in 7, 30 and 90 count bottles NADA 141-455, Approved by FDA

Manufactured for:

Elanco US Inc.

Greenfield, IN 46140

References:

1. Nakao, K., Murase, A., et al. CJ-023,423, a novel, potent and selective prostaglandin EP4 receptor antagonist with antihyperalgesic properties. *The Journal of Pharmacology and Experimental Therapeutics*. 2007; 322(2), 686-694.
2. Murase, A., Okumura, T., et al. Effect of prostanoid EP4 receptor antagonist, CJ-042,794, in rat models of pain and inflammation. *European Journal of Pharmacology*. 2008; 580(1-2), 116-121.
3. Takeuchi, K., S. Kato, et al. Prostaglandin EP receptors involved in modulating gastrointestinal mucosal integrity. *Journal of Pharmacological Sciences*. 2010; 114(3): 248-261.
4. Hatazawa R, Tanaka A, Tanigami M, et al. Cyclooxygenase-2/prostaglandin E₂ accelerates the healing of gastric ulcers via EP4 receptors. *American Journal of Physiology-Gastrointestinal and Liver Physiology*. 2007; 293: G788-G797.
5. Nasrallah R, Hassouneh R, and Hebert R. Chronic kidney disease: targeting prostaglandin E₂ receptors. *American Journal of Physiology Renal Physiology*. 2014; 307: F242-250.
6. Castleberry TA, Lu B, et al. Molecular cloning and functional characterization of the canine prostaglandin E₂ receptor EP4 subtype. *Prostaglandins and Other Lipid Mediators*. 2001; 65: 167-187.
7. http://www.vet.upenn.edu/docs/default-source/VCIC/canine-bpi_userguide.pdf?sfvrsn=0

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February 2018

PA100845X

ARATANA THERAPEUTICS®

Elanco™

Principal Display Panel - Galliprant 20 mg 7 Tablets Box Label

GALLIPRANT® (grapiprant tablets)

20 mg Flavored Tablets

Store at or below 86° F (30° C)

Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

For oral use in dogs only

Case Qty: 48 (1 bottle) cartons

7 flavored tablets per bottle

NADA 141-455

Approved by FDA

Manufactured for:

Elanco US Inc.

Greenfield, IN 46140

1-888-545-5973

YL100844A

GALLIPRANT[®] (grapiprant tablets) 20 mg Flavored Tablets

Store at or below 86° F (30° C)



Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

For oral use in dogs only
Case Qty: 48 (1 bottle) cartons
7 flavored tablets per bottle

NADA 141-455
Approved by FDA



Manufactured for:
Elanco US Inc.
Greenfield, IN 46140
1-888-545-5973
YL100844A



Principal Display Panel - Galliprant 20 mg 7 Tablets Carton Label

Galliprant[®]

(grapiprant tablets)

20 mg

**For oral use
in dogs only**

EP4 Prostaglandin

Receptor Antagonist NSAID

Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

7
FLAVORED
TABLETS

ARATANA
THERAPEUTICS®

Elanco

7 FLAVORED TABLETS

20mg

Galliprant[®]
(grapiprant tablets)

Galliprant[®]
(grapiprant tablets)

Indication: GALLIPRANT is indicated for the control of pain and inflammation associated with osteoarthritis in dogs.

Warnings: Not for use in humans. Keep this and all medications out of reach of children and pets. Consult a physician in case of accidental ingestion by humans.

For use in dogs only. Do not use in cats. Store GALLIPRANT out of reach of dogs and other pets in a secured location in order to prevent accidental ingestion or overdose.

Dosage and Administration: 0.9 mg/lb (2 mg/kg) once daily

Store at or below 86° F (30° C)

Please refer to the package insert for complete information.

NDC 58198-5810-1 SH100845A

Galliprant[®]
(grapiprant tablets)

20mg

For oral use in dogs only

Manufactured for:
Elanco US Inc.
Greenfield, IN 46140
1-888-545-5973

NADA 141-455
Approved by FDA

 7 FLAVORED TABLETS

ARATANA Elanco

Galliprant[®]
(grapiprant tablets)

20mg

For oral use in dogs only

EP4 Prostaglandin Receptor Antagonist NSAID

Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

 7 FLAVORED TABLETS

ARATANA Elanco

Galliprant[®]
(grapiprant tablets)

20mg

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EP4 Prostaglandin Receptor Antagonist NSAID

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 7 FLAVORED TABLETS

ARATANA Elanco

8 54981 00600 7

Principal Display Panel - Galliprant 20 mg 7 Tablets Bottle Label

Galliprant®

(grapiprant tablets)

20 mg

**For oral use
in dogs only**

EP4 Prostaglandin

Receptor Antagonist

NSAID

Caution: Federal (USA)

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licensed veterinarian.

7

**FLAVORED
TABLETS**

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Dosage and Administration: 0.9 mg/lb (2 mg/kg) once daily

Please refer to the package insert for complete information.

**For oral use
in dogs only**

**EP4 Prostaglandin
Receptor Antagonist
NSAID**

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20mg

**7 FLAVORED
TABLETS**

Store at or below:
86° F (30° C)

NADA 141-455
Approved by FDA

Manufactured for:
Elanco US Inc.
Greenfield, IN 46140
1-888-545-5973

Elanco

ARATANA
THE PHARMACEUTICALS COMPANY

YL100843A

Principal Display Panel - Galliprant 20 mg 30 Tablets Box Label

GALLIPRANT® (grapiprant tablets)

20 mg Flavored Tablets

Store at or below 86° F (30° C)

Caution: Federal (USA)
law restricts this drug to
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a licensed veterinarian.

For oral use in dogs only

Case Qty: 48 (1 bottle) cartons

30 flavored tablets per bottle

NADA 141-455

Approved by FDA

Manufactured for:

Elanco US Inc.

Greenfield, IN 46140

1-888-545-5973

YL100844B

GALLIPRANT® (grapiprant tablets)

20 mg Flavored Tablets

Store at or below 86° F (30° C)



Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

For oral use in dogs only
Case Qty: 48 (1 bottle) cartons
30 flavored tablets per bottle

NADA 141-455
Approved by FDA



Manufactured for:
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Greenfield, IN 46140
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YL100844B



Principal Display Panel - Galliprant 20 mg 30 Tablets Carton Label

Galliprant®

(grapiprant tablets)

20 mg

**For oral use
in dogs only**

EP4 Prostaglandin

Receptor Antagonist NSAID

Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

30
 FLAVORED
 TABLETS
 ARATANA
 THERAPEUTICS®
 Elanco



Principal Display Panel - Galliprant 20 mg 30 Tablets Bottle Label

Galliprant®
 (grapiprant tablets)
 20 mg

**For oral use
in dogs only**

EP4 Prostaglandin

Receptor Antagonist

NSAID

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Galliprant[®]
(grapiprant tablets)

20 mg

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EP4 Prostaglandin
Receptor Antagonist
NSAID**

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30 FLAVORED
TABLETS

Store at or below:
86° F (30° C)

NADA 141-455
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Manufactured for:
Elanco US Inc.
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Elanco

ARATANA
LABORATORIES

YL100843B

Principal Display Panel - Galliprant 20 mg 90 Tablets Box Label

GALLIPRANT[®] (grapiprant tablets)

20 mg Flavored Tablets

Store at or below 86° F (30° C)

Caution: Federal (USA)
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a licensed veterinarian.

For oral use in dogs only

Case Qty: 48 (1 bottle) cartons

90 flavored tablets per bottle

NADA 141-455

Approved by FDA

Manufactured for:

Elanco US Inc.

Greenfield, IN 46140

1-888-545-5973

YL100844B

GALLIPRANT[®] (grapiprant tablets)

20 mg Flavored Tablets

Store at or below 86° F (30° C)



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For oral use in dogs only

Case Qty: 48 (1 bottle) cartons
90 flavored tablets per bottle

NADA 141-455

Approved by FDA



Manufactured for:
Elanco US Inc.
Greenfield, IN 46140
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YL100844C



Principal Display Panel - Galliprant 20 mg 90 Tablets Carton Label

Galliprant[®]

(grapiprant tablets)

20 mg

For oral use

in dogs only

EP4 Prostaglandin

Receptor Antagonist NSAID

Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

90

FLAVORED

TABLETS

ARATANA

THERAPEUTICS[®]

Elanco



Principal Display Panel - Galliprant 20 mg 90 Tablets Bottle Label

Galliprant®

(grapiprant tablets)

20 mg

**For oral use
in dogs only**

**EP4 Prostaglandin
Receptor Antagonist
NSAID**

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(grapiprant tablets)

20 mg

For oral use in dogs only
EP4 Prostaglandin Receptor Antagonist NSAID

Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

90 FLAVORED TABLETS

Store at or below:
86° F (30° C)

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Manufactured for:
Elanco US Inc.
Greenfield, IN 46140
1-888-545-5973

Elanco

ARATANA

YL100843C

Principal Display Panel - Galliprant 60 mg 7 Tablets Box Label

GALLIPRANT[®] (grapiprant tablets)

60 mg Flavored Tablets

Store at or below 86° F (30° C)

Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

For oral use in dogs only

Case Qty: 48 (1 bottle) cartons
7 flavored tablets per bottle

NADA 141-455

Approved by FDA

Manufactured for:

Elanco US Inc.

Greenfield, IN 46140

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YL100844D

GALLIPRANT® (grapiprant tablets)

60 mg Flavored Tablets

Store at or below 86° F (30° C)



Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

For oral use in dogs only

Case Qty: 48 (1 bottle) cartons
7 flavored tablets per bottle

NADA 141-455
Approved by FDA



Manufactured for:
Elanco US Inc.
Greenfield, IN 46140
1-888-545-5973
YL100844D



Principal Display Panel - Galliprant 60 mg 7 Tablets Carton Label

Galliprant®

(grapiprant tablets)

60 mg

**For oral use
in dogs only**

EP4 Prostaglandin

Receptor Antagonist NSAID

Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

7
 FLAVORED
 TABLETS
 ARATANA
 THERAPEUTICS®
 Elanco



Principal Display Panel - Galliprant 60 mg 7 Tablets Bottle Label

Galliprant®
 (grapiprant tablets)
60 mg

**For oral use
in dogs only**

EP4 Prostaglandin

Receptor Antagonist

NSAID

Caution: Federal (USA)
law restricts this
drug to use by or
on the order of a
licensed veterinarian.

7
FLAVORED
TABLETS

Indication: GALLIPRANT is indicated for the control of pain and inflammation associated with osteoarthritis in dogs.

Warnings: Not for use in humans. Keep this and all medications out of reach of children and pets. Consult a physician in case of accidental ingestion by humans. **For use in dogs only. Do not use in cats.**

Dosage and Administration: 0.9 mg/lb (2 mg/kg) once daily

Please refer to the package insert for complete information.

**For oral use
in dogs only**

60 mg

**EP4 Prostaglandin
Receptor Antagonist
NSAID**

Caution: Federal (USA)
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of a licensed veterinarian.

7 FLAVORED
TABLETS

Store at or below:
86° F (30° C)
NADA 141-455
Approved by FDA
Manufactured for:
Elanco US Inc.
Greenfield, IN 46140
1-888-545-5973

Elanco

ARATANA
THERAPEUTICS

YL100843D

Principal Display Panel - Galliprant 60 mg 30 Tablets Box Label

GALLIPRANT® (grapiprant tablets)

60 mg Flavored Tablets

Store at or below 86° F (30° C)

Caution: Federal (USA)
law restricts this drug to
use by or on the order of

a licensed veterinarian.

For oral use in dogs only

Case Qty: 48 (1 bottle) cartons

30 flavored tablets per bottle

NADA 141-455

Approved by FDA

Manufactured for:

Elanco US Inc.

Greenfield, IN 46140

1-888-545-5973

YL100844E

GALLIPRANT[®] (grapiprant tablets)

60 mg Flavored Tablets

Store at or below 86° F (30° C)



Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

For oral use in dogs only

Case Qty: 48 (1 bottle) cartons
30 flavored tablets per bottle

NADA 141-455

Approved by FDA



Manufactured for:
Elanco US Inc.
Greenfield, IN 46140
1-888-545-5973
YL100844E



Principal Display Panel - Galliprant 60 mg 30 Tablets Carton Label

Galliprant[®]

(grapiprant tablets)

60 mg

**For oral use
in dogs only**

EP4 Prostaglandin

Receptor Antagonist NSAID

Caution: Federal (USA) law
restricts this drug to use by
or on the order of a
licensed veterinarian.

30
FLAVORED
TABLETS

ARATANA
THERAPEUTICS[®]

Elanco



Principal Display Panel - Galliprant 60 mg 30 Tablets Bottle Label

Galliprant®

(grapiprant tablets)

60 mg

**For oral use
in dogs only**

**EP4 Prostaglandin
Receptor Antagonist
NSAID**

Caution: Federal (USA)
law restricts this
drug to use by or
on the order of a
licensed veterinarian.

FLAVORED
TABLETS

Indication: GALLIPRANT is indicated for the control of pain and inflammation associated with osteoarthritis in dogs.

Warnings: Not for use in humans. Keep this and all medications out of reach of children and pets. Consult a physician in case of accidental ingestion by humans. **For use in dogs only. Do not use in cats.**

Dosage and Administration:
0.9 mg/lb (2 mg/kg) once daily

Please refer to the package insert for complete information.

Galliprant
(grapiprant tablets)

60 mg

For oral use in dogs only
EP4 Prostaglandin Receptor Antagonist NSAID

Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.


90 FLAVORED TABLETS

Store at or below:
86° F (30° C)
NADA 141-455
Approved by FDA
Manufactured for:
Elanco US Inc.
Greenfield, IN 46140
1-888-545-5973

Elanco


YL100843F

Principal Display Panel - Galliprant 20 mg 90 Tablets Box Label

GALLIPRANT® (grapiprant tablets)

60 mg Flavored Tablets

Store at or below 86° F (30° C)

Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

For oral use in dogs only

Case Qty: 48 (1 bottle) cartons

90 flavored tablets per bottle

NADA 141-455

Approved by FDA

Manufactured for:

Elanco US Inc.

Greenfield, IN 46140

1-888-545-5973

YL100844F

GALLIPRANT® (grapiprant tablets)

60 mg Flavored Tablets

Store at or below 86° F (30° C)



Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

For oral use in dogs only

Case Qty: 48 (1 bottle) cartons
90 flavored tablets per bottle

NADA 141-455
Approved by FDA



Manufactured for:
Elanco US Inc.
Greenfield, IN 46140
1-888-545-5973
YL100844F



Principal Display Panel - Galliprant 60 mg 90 Tablets Carton Label

Galliprant®

(grapiprant tablets)

60 mg

**For oral use
in dogs only**

EP4 Prostaglandin

Receptor Antagonist NSAID

Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

90
FLAVORED
TABLETS
ARATANA
THERAPEUTICS®
Elanco



Principal Display Panel - Galliprant 60 mg 90 Tablets Bottle Label

Galliprant®
(grapiprant tablets)

60 mg

**For oral use
in dogs only**

**EP4 Prostaglandin
Receptor Antagonist**

NSAID

Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

90
FLAVORED
TABLETS

Indication: GALLIPRANT is indicated for the control of pain and inflammation associated with osteoarthritis in dogs.

Warnings: Not for use in humans. Keep this and all medications out of reach of children and pets. Consult a physician in case of accidental ingestion by humans. **For use in dogs only. Do not use in cats.**

Dosage and Administration: 0.9 mg/lb (2 mg/kg) once daily

Please refer to the package insert for complete information.

Galliprant[®]
(grapiprant tablets)

60mg

For oral use in dogs only
EP4 Prostaglandin Receptor Antagonist NSAID

Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

30 FLAVORED TABLETS

Store at or below:
86° F (30° C)

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Approved by FDA

Manufactured for:
Elanco US Inc.
Greenfield, IN 46140
1-888-545-5973

Elanco

ARATANA
LABORATORIES

YL100843E

Principal Display Panel - Galliprant 100 mg 7 Tablets Box Label

GALLIPRANT[®] (grapiprant tablets)

100 mg Flavored Tablets

Store at or below 86° F (30° C)

Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

For oral use in dogs only

Case Qty: 48 (1 bottle) cartons

7 flavored tablets per bottle

NADA 141-455

Approved by FDA

Manufactured for:

Elanco US Inc.

Greenfield, IN 46140

1-888-545-5973

YL100844G

GALLIPRANT[®] (grapiprant tablets) 100 mg Flavored Tablets

Store at or below 86° F (30° C)



Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

For oral use in dogs only
Case Qty: 48 (1 bottle) cartons
7 flavored tablets per bottle

NADA 141-455
Approved by FDA



Manufactured for:
Elanco US Inc.
Greenfield, IN 46140
1-888-545-5973
YL100844G



Principal Display Panel - Galliprant 100 mg 7 Tablets Carton Label

Galliprant[®]

(grapiprant tablets)

100 mg

**For oral use
in dogs only**

EP4 Prostaglandin

Receptor Antagonist NSAID

Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

7
FLAVORED
TABLETS

ARATANA
THERAPEUTICS®

Elanco



Principal Display Panel - Galliprant 100 mg 7 Tablets Bottle Label

Galliprant®

(grapiprant tablets)

100 mg

**For oral use
in dogs only**

**EP4 Prostaglandin
Receptor Antagonist
NSAID**

Caution: Federal (USA)
law restricts this
drug to use by or
on the order of a
licensed veterinarian.

7
FLAVORED
TABLETS

Indication: GALLIPRANT is indicated for the control of pain and inflammation associated with osteoarthritis in dogs.

Warnings: Not for use in humans. Keep this and all medications out of reach of children and pets. Consult a physician in case of accidental ingestion by humans. **For use in dogs only.** Do not use in cats.

Dosage and Administration:
0.9 mg/lb (2 mg/kg) once daily

Please refer to the package insert for complete information.

Galliprant[®]
(grapiprant tablets)

100 mg

**For oral use in dogs only
EP4 Prostaglandin Receptor
Antagonist NSAID**

Caution: Federal (USA)
law restricts this drug to
use by or on the order of
a licensed veterinarian.

**7 FLAVORED
TABLETS**

Store at or below:
86° F (30° C)
NADA 141-455
Approved by FDA
Manufactured for:
Elanco US Inc.
Greenfield, IN 46140
1-888-545-5973

Elanco

ARATANA

YL100843G

Principal Display Panel - Galliprant 100 mg 30 Tablets Box Label

GALLIPRANT[®] (grapiprant tablets)

100 mg Flavored Tablets

Store at or below 86° F (30° C)

Caution: Federal (USA)
law restricts this drug to
use by or on the order of
a licensed veterinarian.

For oral use in dogs only

Case Qty: 48 (1 bottle) cartons
30 flavored tablets per bottle

NADA 141-455

Approved by FDA

Manufactured for:

Elanco US Inc.

Greenfield, IN 46140

1-888-545-5973

YL100844H

GALLIPRANT® (grapiprant tablets)

100 mg Flavored Tablets

Store at or below 86° F (30° C)



Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

For oral use in dogs only

Case Qty: 48 (1 bottle) cartons
30 flavored tablets per bottle

NADA 141-455

Approved by FDA



Manufactured for:

Elanco US Inc.

Greenfield, IN 46140

1-888-545-5973

YL100844H



Principal Display Panel - Galliprant 100 mg 30 Tablets Carton Label

Galliprant®

(grapiprant tablets)

100 mg

**For oral use
in dogs only**

EP4 Prostaglandin

Receptor Antagonist NSAID

Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

30
FLAVORED
TABLETS

ARATANA
THERAPEUTICS®

Elanco



Principal Display Panel - Galliprant 100 mg 30 Tablets Bottle Label

Galliprant®

(grapiprant tablets)

100 mg

**For oral use
in dogs only**

EP4 Prostaglandin

Receptor Antagonist

NSAID

Caution: Federal (USA)
law restricts this
drug to use by or
on the order of a
licensed veterinarian.

30

FLAVORED
TABLETS

Indication: GALLIPRANT is indicated for the control of pain and inflammation associated with osteoarthritis in dogs.

Warnings: Not for use in humans. Keep this and all medications out of reach of children and pets. Consult a physician in case of accidental ingestion by humans. **For use in dogs only. Do not use in cats.**

Dosage and Administration:
0.9 mg/lb (2 mg/kg) once daily

Please refer to the package insert for complete information.

Galliprant®
(grapiprant tablets)

100 mg

For oral use in dogs only
EP4 Prostaglandin Receptor Antagonist NSAID

Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

30 FLAVORED TABLETS

Store at or below:
86° F (30° C)
NADA 141-455
Approved by FDA
Manufactured for:
Elanco US Inc.
Greenfield, IN 46140
1-888-545-5973

Elanco

ARATANA

YL100843H

Principal Display Panel - Galliprant 20 mg 90 Tablets Box Label

GALLIPRANT® (grapiprant tablets)

100 mg Flavored Tablets

Store at or below 86° F (30° C)

Caution: Federal (USA)
law restricts this drug to
use by or on the order of
a licensed veterinarian.

For oral use in dogs only

Case Qty: 48 (1 bottle) cartons

90 flavored tablets per bottle

NADA 141-455

Approved by FDA

Manufactured for:

Elanco US Inc.

Greenfield, IN 46140

1-888-545-5973

YL100844I

GALLIPRANT® (grapiprant tablets)

100 mg Flavored Tablets

Store at or below 86° F (30° C)



Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

For oral use in dogs only

Case Qty: 48 (1 bottle) cartons
90 flavored tablets per bottle

NADA 141-455

Approved by FDA



Manufactured for:
Elanco US Inc.
Greenfield, IN 46140
1-888-545-5973
YL100844I



Principal Display Panel - Galliprant 100 mg 90 Tablets Carton Label

Galliprant®

(grapiprant tablets)

100 mg

For oral use
in dogs only

EP4 Prostaglandin

Receptor Antagonist NSAID

Caution: Federal (USA) law
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or on the order of a
licensed veterinarian.

90
FLAVORED
TABLETS

ARATANA
THERAPEUTICS®

Elanco

90 FLAVORED TABLETS

100mg

Galliprant®
(grapiprant tablets)

Galliprant®
(grapiprant tablets)

Galliprant®
(grapiprant tablets)

Galliprant®
(grapiprant tablets)

Indication: GALLIPRANT is indicated for the control of pain and inflammation associated with osteoarthritis in dogs.

Warnings: Not for use in humans. Keep this and all medications out of reach of children and pets. Consult a physician in case of accidental ingestion by humans. **For use in dogs only. Do not use in cats.** Store GALLIPRANT out of reach of dogs and other pets in a secured location in order to prevent accidental ingestion or overdose.

Dosage and Administration:
0.9 mg/lb (2 mg/kg) once daily

Store at or below 86° F (30° C)

Please refer to the package insert for complete information.

NDC 58198-5812-3 SH1008451

8 54981 00608 3

For oral use in dogs only

100mg

For oral use in dogs only

100mg

For oral use in dogs only

100mg

Manufactured for:
Elanco US Inc.
Greenfield, IN 46140
1-888-545-5973

NADA 141-455
Approved by FDA

90 FLAVORED TABLETS

ARATANA THERAPEUTICS

Elanco

90 FLAVORED TABLETS

ARATANA THERAPEUTICS

Elanco

90 FLAVORED TABLETS

ARATANA THERAPEUTICS

Elanco

Principal Display Panel - Galliprant 100 mg 90 Tablets Bottle Label

Galliprant®

(grapiprant tablets)

100 mg

**For oral use
in dogs only**

EP4 Prostaglandin

Receptor Antagonist

NSAID

Caution: Federal (USA)

law restricts this drug to use by or on the order of a licensed veterinarian.

90
FLAVORED
TABLETS

Only Sold
in Carton

Indication: GALLIPRANT is indicated for the control of pain and inflammation associated with osteoarthritis in dogs.

Warnings: Not for use in humans. Keep this and all medications out of reach of children and pets. Consult a physician in case of accidental ingestion by humans. **For use in dogs only. Do not use in cats.**

Dosage and Administration:
0.9 mg/lb (2 mg/kg) once daily

Please refer to the package insert for complete information.

Galliprant®
(grapiprant tablets)

100mg

For oral use in dogs only

EP4 Prostaglandin Receptor Antagonist NSAID

Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.



90 FLAVORED TABLETS

Store at or below:
86° F (30° C)
NADA 141-455
Approved by FDA
Manufactured for:
Elanco US Inc.
Greenfield, IN 46140
1-888-545-5973

Elanco

ARATANA

YL100843I

GALLIPRANT

grapiprant tablet

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:58 198 -58 10
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Grapiprant (UNII: J9F5ZPH7NB) (Grapiprant - UNII:J9F5ZPH7NB)	Grapiprant	20 mg

Product Characteristics

Color	brown (Brown)	Score	2 pieces
Shape	OVAL (OVAL)	Size	12mm
Flavor		Imprint Code	20;mg;G;G
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58 198-58 10-4	48 in 1 BOX		
1	NDC:58 198-58 10-1	1 in 1 CARTON		
1		7 in 1 BOTTLE		
2	NDC:58 198-58 10-5	48 in 1 BOX		
2	NDC:58 198-58 10-2	1 in 1 CARTON		
2		30 in 1 BOTTLE		
3	NDC:58 198-58 10-6	48 in 1 BOX		
3	NDC:58 198-58 10-3	1 in 1 CARTON		
3		90 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA141455	01/03/2016	

GALLIPRANT

grapiprant tablet

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:58 198-58 11
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Grapiprant (UNII: J9F5ZPH7NB) (Grapiprant - UNII:J9F5ZPH7NB)	Grapiprant	60 mg

Product Characteristics

Color	brown (Brown)	Score	2 pieces
Shape	OVAL (OVAL)	Size	18mm
Flavor		Imprint Code	60;mg;G;G
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58 198-58 11-4	48 in 1 BOX		
1	NDC:58 198-58 11-1	1 in 1 CARTON		
1		7 in 1 BOTTLE		
2	NDC:58 198-58 11-5	48 in 1 BOX		
2	NDC:58 198-58 11-2	1 in 1 CARTON		
2		30 in 1 BOTTLE		
3	NDC:58 198-58 11-6	48 in 1 BOX		
3	NDC:58 198-58 11-3	1 in 1 CARTON		
3		90 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA141455	01/03/2016	

GALLIPRANT

grapiprant tablet

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:58 198-58 12
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Grapiprant (UNII: J9F5ZPH7NB) (Grapiprant - UNII:J9F5ZPH7NB)	Grapiprant	100 mg

Product Characteristics

Color	brown (Brown)	Score	2 pieces
Shape	OVAL (OVAL)	Size	23mm
Flavor		Imprint Code	100;mg;G;G
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58 198-58 12-4	48 in 1 BOX		
1	NDC:58 198-58 12-1	1 in 1 CARTON		
1		7 in 1 BOTTLE		
2	NDC:58 198-58 12-5	48 in 1 BOX		
2	NDC:58 198-58 12-2	1 in 1 CARTON		
2		30 in 1 BOTTLE		

3	NDC:58 198-58 12-6	48 in 1 BOX		
3	NDC:58 198-58 12-3	1 in 1 CARTON		
3		90 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA141455	01/03/2016	

Labeler - Elanco US Inc. (966985624)

Revised: 5/2018

Elanco US Inc.