

Date of Approval: SEP 23 2008

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 141-230

PREVICOX

Firocoxib
Chewable Tablets
Dogs

Effect of Supplement: This supplement provides for the addition of a new indication for the control of postoperative pain and inflammation associated with orthopedic surgery in dogs.

Sponsored by:

Merial Ltd.

NADA-141-230
FDA-2008-N-0039

FOIS

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I. GENERAL INFORMATION:

- A. File Number:** NADA 141-230
- B. Sponsor:** Merial Ltd.
3239 Satellite Blvd., Bldg. 500
Duluth, GA 30096-4640
- Drug Labeler Code: 050604
- C. Proprietary Name(s):** PREVICOX
- D. Established Name(s):** firocoxib
- E. Pharmacological Category:** Non-steroidal anti-inflammatory drug (NSAID)
- F. Dosage Form(s):** Single-scored chewable tablet
- G. Amount of Active Ingredient(s):** Each tablet contains 57 or 227 mg firocoxib.
- H. How Supplied:** The product is available as 57 and 227 mg round, single-scored tablets in 60-count bottles, and in 10-count and 30-count blister packages.
- I. How Dispensed:** Rx
- J. Dosage(s):** The recommended dosage of PREVICOX (firocoxib) for oral administration in dogs is 2.27 mg/lb (5.0 mg/kg) body weight once daily as needed for osteoarthritis and for 3 days as needed for postoperative pain and inflammation associated with soft-tissue and orthopedic surgery. The dogs can be treated with PREVICOX (firocoxib) approximately two hours prior to surgery. The tablets are scored and dose should be calculated in half tablet increments. PREVICOX Chewable Tablets can be administered with or without food. Use the lowest effective dose for the shortest period of time.
- K. Route(s) of Administration:** Oral

- L. Species/Class(es):** Dogs
- M. Indication(s):** PREVICOX Chewable Tablets are indicated for the control of pain and inflammation associated with osteoarthritis and **for the control of postoperative pain and inflammation associated with soft-tissue and orthopedic surgery in dogs.**
- N. Effect(s) of Supplement:** This supplement provides for the addition of a new indication for the control of postoperative pain and inflammation associated with orthopedic surgery in dogs.

II. EFFECTIVENESS:

A. Dosage Characterization:

This supplemental approval does not change the previously approved dosage of 2.27 mg/lb (5.0 mg/kg) administered orally once-daily. The Freedom of Information (FOI) Summary for the original approval of NADA 141-230 dated July 21, 2004, contains the dosage characterization information for the 2.27 mg/lb (5.0 mg/kg) oral, once daily dose of PREVICOX Chewable Tablets as needed for the control of pain and inflammation associated with osteoarthritis.

B. Substantial Evidence:

1. Type of Study: Field Study

- a. **Title:** “A Study to Demonstrate the Efficacy and Safety of Firocoxib for Control of Postoperative Pain and Inflammation in Dogs.”

b. **Investigators and Study Locations:**

Dr. Kinsey L. Phillips Commerce, GA	Dr. Joachim Lopes de Lima Lattes-Montpellier, France
Dr. Roger S. Sifferman Springfield, MO	Dr. Ulrich Rytz Bern, Switzerland
Dr. C. H. Tangner Oklahoma City, OK	Dr. Ray Rudd Peachtree City, GA
Dr. Nicolas Diss Thionville, France	Dr. Enrico Stefanelli Roma, Italy
Dr. James K. Schuessler Kirkwood, MO	Dr. Janine Guaguère Lomme, France
Dr. Sabine Tacke	Dr. Bertrand Pucheu

Gießen, Germany	La Madeleine, France
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- c. **Study Design:** This was a double-blinded, multi-center field study in which PREVICOX was tested against a sham-dosed control. An add-on study design with rescue was used, where the effectiveness of firocoxib plus the standard of care was compared to a control group receiving the standard of care. All dogs could receive supplemental pain medication (rescue) at any time, as indicated. Enrolled dogs underwent an arthotomy and various surgical procedures to stabilize the joint including fabellar suture and/or imbrication, fibular head transposition, tibial plateau leveling osteotomy (TPLO) and “over the top” technique.
- 1) **Objective:** To demonstrate clinical effectiveness and field safety of firocoxib when administered orally once daily at 2.27 mg/lb (5 mg/kg) body weight, starting 2 hours (+/- 30 min) prior to surgery and continuing for 2 additional days, for the control of postoperative pain and inflammation associated with orthopedic surgery.
 - 2) **Study Animals:** Out of 226 enrolled in the study that underwent surgery, 220 client-owned dogs were evaluated for effectiveness. Six dogs were not included for effectiveness due to protocol violations, dropouts, or missing data. Dogs ranged in age from 1 to 11.9 years in the PREVICOX-treated groups and 0.7 to 17 years in the control group.
 - 3) **Treatment Groups:** The dogs were randomly allocated to two treatment groups. All dogs received standard of care appropriate to the surgical procedure. Anesthetic protocols included morphine administrations at approximately 0.11 mg/lb (approximately 0.25 mg/kg) prior to surgery and at extubation. Dogs in the PREVICOX group also received firocoxib at 2.27 mg/lb (5.0 mg/kg) orally once on Day 0 (approximately 2 hours prior to their surgical procedures) and then orally once daily through Day 2. Dogs in the control group received the standard of care and sham-dosing.
 - 4) **Drug Administration:** Dogs in the PREVICOX group received a dose of 2.27 mg/lb (5.0 mg/kg) orally approximately 2 hours prior to surgery and then orally once daily through Day 2. Dogs in the control group were sham-dosed orally approximately 2 hours prior to surgery and then orally once daily through Day 2.
 - 5) **Measurements and Observations:**
The animals were assessed for pain using the Glasgow Composite Pain Scale (GCPS) and Visual Analog Scale (VAS) at the following time points: once between Days -3 and 0; Day 0 - at approximately 90 minutes, 3, 5, 7, and 9 hours post-extubation; Day 1 - at approximately 2 and 10

hours post-treatment; and Day 2 - at approximately 2 hours post-treatment. The animals were rescued if they scored ≥ 8 on the GCPS, or if the clinical investigator felt the dog in question was painful enough to warrant rescue medication. Rescued dogs or dogs removed due to adverse events were considered treatment failures. These dogs were assessed for pain through the end of the study to ensure proper pain control.

All enrolled dogs received general health evaluations prior to surgery and in conjunction with the pain assessment time points. Physical examinations were conducted once between Days -3 and 0 and once daily on Days 1 and 2. Blood for hematology and blood chemistry analyses, and urine for urinalyses were obtained once pre-surgery and once on Day 2.

The GCPS is a validated pain assessment scale based on a composite score for clinicians to use in determining whether a dog is in pain and requires analgesic drug administration. The composite score is based on six categories:

- (I) Vocalization - Is the dog: quiet, crying or whimpering, groaning, or screaming?
- (II) Attention to wound area - Is the dog: ignoring any wound or painful area, looking at the wound or painful area, licking the wound or painful area, rubbing the wound or painful area, or chewing the wound or painful area?
- (III) Mobility - When the dog walks/rises is it: normal, lame, slow or reluctant, stiff, or refusing to move?
- (IV) Response to touch - Does the dog: do nothing, look around, flinch, growl or guard the area, snap, or cry?
- (V) Demeanor - Is the dog: happy and content or happy and bouncy, quiet, indifferent or non-responsive to surroundings, nervous or anxious or fearful, or depressed or non-responsive to stimulation?
- (VI) Posture and Activity - Is the dog: comfortable, unsettled, restless, hunched or tense, or rigid?

Pain was also assessed using a VAS. The clinical investigators made marks which corresponded to the dogs' perceived pain on a 100 mm horizontal line. In this study, the following clinical signs were used to evaluate the dogs' pain: panting, restlessness, vocalization, looking at or licking at the wound, biting, anxious appearance, reluctance to move, and/or inappetance.

6) Statistical Methods

The definition of effectiveness for this study was a success/failure variable based on the successful completion of the study and the need for rescue medication. This variable was analyzed using a generalized linear mixed

model with binomial error function and logit link function. The statistical model included treatment as a fixed effect, and site and site by treatment interaction as random effects.

The secondary effectiveness variables GCPS Total Score and VAS were analyzed using repeated measures analysis of variance beginning with the Day 0, 5 hour (\pm 30 minutes) time point; data from the time points prior were not included in the analysis. The statistical model for both variables included treatment, time, study site, and all interactions. Treatment, time, and the treatment by time interaction were fixed effects; study site and all interactions with study site were random effects. The last post-treatment (post-surgery) observations for GCPS Total Score and VAS were carried forward in case of missing observations due to treatment failure (rescue medication), protocol violators, early withdrawal for adverse events, or apparent lack of effectiveness.

d. Results

Two hundred twenty dogs (220) were included in the effectiveness database (116 PREVICOX cases). A total of 226 dogs were included in the field safety database (118 PREVICOX cases). The difference between treatments was significantly different ($p = 0.0050$) with respect to the success/failure variable used as the definition of effectiveness. Thirteen of the 116 (11.2%) PREVICOX-treated cases and 39 out of 104 (37.5%) control dogs were treatment failures, as shown in Table 1.

Table 1. Treatment Success in Firocoxib and Control Groups.

Treatment	Treatment Success ^a		Total
	Success	Failure	
Firocoxib ^b	103 (89.66%)	13 (11.2%)	116
Control	65 (62.14%)	39 (37.5%)	104
Total number of cases			220

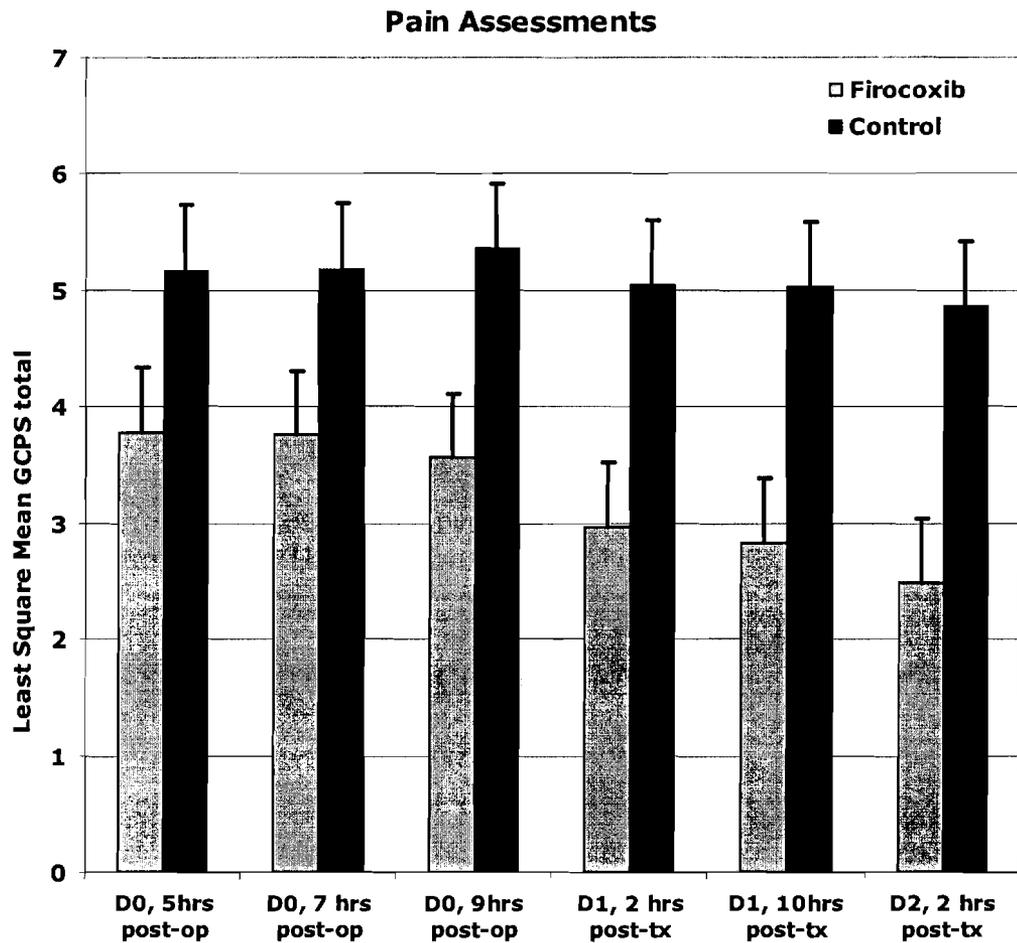
^a The difference in proportions of rescue was statistically significant ($p = 0.0050$) using a generalized linear mixed model with logit link function.

^b One firocoxib case was a treatment failure due to adverse reactions.

Of the 220 dogs in the effectiveness database, 219 dogs were included in the secondary analysis of GCPS Total Score, VAS and individual GCPS category scores. The results from the repeated measures analysis of variance for GCPS total scores across time showed that the least squares means GCPS Total Scores were consistently lower ($p < 0.05$) among dogs that received firocoxib

in addition to standard of care compared to dogs that received standard of care alone (control group). This is shown in Figure 1.

Figure 1. Mean GCPS Scores by Treatment Group at Each Assessment Time Point.



Analyses of pre-surgery and Day 2 hematology, chemistry, and urine specific gravity data were performed. There were six PREVICOX cases and one control case with normal pre- and elevated post-study BUN values.

- e. **Adverse Reactions:** The most commonly-reported adverse reactions were diarrhea and bruising at the surgery site. The adverse reactions and the numbers of dogs experiencing each are summarized in Table 2. Some dogs experienced more than one adverse reaction during the study (e.g., vomiting multiple times).

Table 2. Adverse Reactions Reported in the Orthopedic Surgery Field Study.

Adverse Reactions	Firocoxib Group n=118	Control Group ^a n=108
vomiting	1	0
diarrhea	2 ^b	1
bruising at surgery site	2	3
inappetance/decreased appetite	1	2
pyrexia	0	1
incision swelling, redness	9	5
oozing incision	2	0

A case may be represented in more than one category.

^a Sham-dosed (pilled)

^b one dog had hemorrhagic gastroenteritis

- f. **Conclusions:** Treatment with PREVICOX at a dose of 2.27 mg/lb (5.0 mg/kg) body weight orally once daily starting at approximately 2 hours prior to surgery and continuing for two additional days was well-tolerated. PREVICOX plus the standard of care was shown to be statistically significantly effective when compared to the sham-dosed control (p = 0.0050) receiving the standard of care. GCPS scores indicated that at each time point, PREVICOX-treated dogs had lower pain scores than the control dogs.

III. TARGET ANIMAL SAFETY:

CVM did not require target animal safety studies for this supplemental approval. The FOI Summary for the original approval of NADA 141-230 dated July 21, 2004, contains a summary of target animal safety studies in support of PREVICOX Chewable Tablets in dogs at an oral, once-daily dose of 2.27 mg/lb (5.0 mg/kg).

IV. HUMAN FOOD SAFETY:

This drug is intended for use in dogs, which are non-food animals. Because this new animal drug is not intended for use in food producing animals, CVM did not require data pertaining to drug residues in food (i.e., human food safety) for approval of this NADA.

V. USER SAFETY:

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to PREVICOX:

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

VI. AGENCY CONCLUSIONS:

The data submitted in support of this NADA satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514. The data demonstrate that PREVICOX, when used according to the label, are safe and effective for the control of postoperative pain and inflammation associated with orthopedic surgery in dogs.

A. Marketing Status:

The drug is restricted to use by or on the order of, a licensed veterinarian because professional expertise is needed to diagnose and provide guidance in the control of postoperative pain. Furthermore, the veterinarian monitors patients for possible adverse effects of the drug.

B. Exclusivity:

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act, this approval qualifies for THREE years of marketing exclusivity beginning on the date of the approval. The three years of marketing exclusivity apply only to the new indication for the control of postoperative pain and inflammation associated with orthopedic surgery for which this supplement is approved.

C. Supplemental Applications:

This supplemental NADA did not require a reevaluation of the safety or effectiveness data in the original NADA (21 CFR 514.106(b)(2)).

D. Patent Information:

PREVICOX is under the following U.S. patent numbers:

<u>U.S. Patent Number</u>	<u>Date of Expiration</u>
5,981,576	July 21, 2018
6,541,646	October 8, 2019
6,677,373	October 8, 2019

VII. ATTACHMENTS:

Facsimile Labeling:

Package Insert
Owner Information Sheet

Carton Labels:

60 tablets—57 mg
60 tablets—227 mg
30 tablets—57 mg
30 tablets—227 mg

10 tablets—57 mg

10 tablets—227 mg

Bottle Labels:

60 tablets—57 mg

60 tablets—227 mg

Blister Labels:

10 tablets—57 mg

10 tablets—227 mg

Display cartons:

57 mg

227 mg

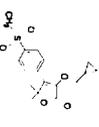
PREVICOX®



PREVICOX® (firocoxib) Chewable Tablets

For oral use in dogs only

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



Pharmacokinetics: The in vivo bioavailability of PREVICOX (firocoxib) is approximately 100% in dogs. The elimination half-life of PREVICOX is approximately 11 hours in dogs. The elimination half-life of PREVICOX is approximately 11 hours in dogs. The elimination half-life of PREVICOX is approximately 11 hours in dogs.

Indications and Usage: PREVICOX (firocoxib) is indicated for the treatment of osteoarthritis in dogs. It is not indicated for the treatment of osteoarthritis in cats. It is not indicated for the treatment of osteoarthritis in cats.

Warnings: Do not use in horses. Keep the oral and rectal cavities out of the reach of children. PREVICOX (firocoxib) is a non-steroidal anti-inflammatory drug (NSAID). It is not indicated for the treatment of osteoarthritis in cats.

Adverse Reactions: The most common adverse reactions observed in dogs treated with PREVICOX (firocoxib) are vomiting, diarrhea, and decreased appetite. Other adverse reactions include lethargy, anorexia, and weight loss.

How to Use: PREVICOX (firocoxib) Chewable Tablets are given orally to dogs. The recommended dosage is 5 mg/kg once daily. The recommended dosage is 5 mg/kg once daily.

Adverse Reactions	PREVICOX (firocoxib) Chewable Tablets	Control Group
Vomiting	5	1
Diarrhea	3	1
Decreased Appetite or Anorexia	3	1
Lethargy	2	1
Weight Loss	1	0
Other Adverse Reactions	1	0

Postoperative Pain Relief Studies: PREVICOX (firocoxib) Chewable Tablets were evaluated in two studies. In the first study, PREVICOX (firocoxib) Chewable Tablets were compared to a control group. In the second study, PREVICOX (firocoxib) Chewable Tablets were compared to a control group.

Adverse Reactions Seen in the Osteopathic Surgery: The most common adverse reactions observed in dogs treated with PREVICOX (firocoxib) are vomiting, diarrhea, and decreased appetite. Other adverse reactions include lethargy, anorexia, and weight loss.

Adverse Reactions	Firocoxib Group	Control Group
Vomiting	18	0
Diarrhea	7	1
Decreased Appetite or Anorexia	2	3
Lethargy	2	2
Weight Loss	0	1
Other Adverse Reactions	9	5

How to Use: PREVICOX (firocoxib) Chewable Tablets are given orally to dogs. The recommended dosage is 5 mg/kg once daily. The recommended dosage is 5 mg/kg once daily.

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100-172-04
M 01 0309

Previcox
(firocoxib)



Information for Dog Owners about PREVICOX® (firocoxib) Chewable Tablets

PREVICOX Chewable Tablets are used for the control of pain and inflammation due to osteoarthritis or associated with soft-tissue and orthopedic surgery in your dog.

This summary contains important information about PREVICOX. You should read this information before you start giving your dog PREVICOX tablets and review it each time your prescription is refilled. This sheet is provided only as a summary and does not take the place of instructions from your veterinarian. Talk to your veterinarian if you do not understand any of this information or you want to know more about PREVICOX.

What is PREVICOX?

PREVICOX is a veterinary prescription non-steroidal anti-inflammatory drug (NSAID) used to control pain and inflammation due to osteoarthritis, or associated with soft-tissue and orthopedic surgery in dogs.

Osteoarthritis is a painful condition caused by "wear and tear" of cartilage and other parts of the joints that may result in the following changes or signs in your dog:

- Limping or lameness.
- Decreased activity or exercise (reluctance to stand, climb stairs, jump or run, or difficulty in performing these activities).
- Stiffness or decreased movement of joints.

PREVICOX is indicated for the control of postoperative pain and inflammation following soft-tissue and orthopedic surgeries (e.g., spays, cruciate ligament repair). Your veterinarian may administer PREVICOX before the procedure and recommend that the dog be treated for a few days after going home.

What kind of results can I expect when my dog is on PREVICOX for osteoarthritis?

While PREVICOX is not a cure for osteoarthritis, it can control the pain and inflammation and improve your dog's mobility.

- Response varies from dog to dog, but improvement can be quite dramatic.
- In most dogs, improvement can be seen within days.
- If PREVICOX is discontinued or not given as directed, your dog's pain and inflammation may return.

What kind of results can I expect when my dog is on PREVICOX for the control of pain and inflammation following soft-tissue and orthopedic surgery?

- PREVICOX Chewable Tablets allow your dog to recover more comfortably by controlling pain and inflammation following soft-tissue and orthopedic surgery.
- Control of pain and inflammation may vary from dog to dog.
- If PREVICOX Chewable Tablets are not given according to your veterinarian's directions, your dog's pain may return.
- Consult your veterinarian if your dog appears to be uncomfortable.

Which dogs should not take PREVICOX?

Your dog should not be given PREVICOX if he/she:

- Has an allergic reaction to firocoxib, the active ingredient in PREVICOX.
- Has had an allergic reaction (such as hives, facial swelling, or red or itchy skin) to aspirin or other NSAIDs.
- Is presently taking aspirin, other NSAIDs, or corticosteroids.
- Is under 12.5 pounds in body weight.
- Has pre-existing kidney or liver disease.
- Has decreased appetite, vomiting or diarrhea.

PREVICOX should only be given to dogs.

People should not take PREVICOX. Keep PREVICOX and all medications out of the reach of children. Call your physician immediately if you accidentally take PREVICOX.

What to tell/ask your veterinarian before giving PREVICOX.

Talk to your veterinarian about:

- The signs of osteoarthritis you have observed in your dog, such as limping or stiffness.
- The importance of weight control in the management of osteoarthritis.
- What tests might be done before PREVICOX is prescribed.
- How often your dog may need to be examined by your veterinarian.
- The risks and benefits of using PREVICOX. Serious adverse reactions, including death, have been associated with PREVICOX administration at doses above the recommended dose in puppies less than seven months of age.

Tell your veterinarian if your dog is currently experiencing or has ever had the following medical problems:

- Any side effects from taking PREVICOX or other NSAIDs, such as aspirin.
- Any digestive upset (vomiting and/or diarrhea).
- Any kidney disease.
- Any liver disease.

Tell your veterinarian about:

- Any other medical problems or allergies that your dog has now or has had in the past.
- All medicines that you are giving or plan to give to your dog, including those you can get without a prescription and any dietary supplements.

Tell your veterinarian if your dog:

- Is under 7 months of age.
- Is pregnant, nursing or if you plan to breed your dog.

How to give PREVICOX to your dog.

PREVICOX should be given according to your veterinarian's instructions. Do not change the way you give PREVICOX to your dog without first speaking with your veterinarian. Your veterinarian will tell you what amount of PREVICOX is right for your dog and for how long it should be given. Most dogs will take PREVICOX Chewable Tablets from your hand, or you can place the tablet in your dog's mouth. PREVICOX may be given with or without food.

What are the possible side effects that may occur in my dog during PREVICOX therapy?

PREVICOX, like other NSAIDs, may cause some side effects. Serious side effects associated with NSAID therapy in dogs can occur with or without warning, and, in rare situations, result in death. The most common side effects associated with PREVICOX therapy involve the digestive tract (vomiting and decreased food consumption). Liver and kidney problems have also been reported with NSAIDs. Look for the following side effects that may indicate your dog is having a problem with PREVICOX:

- Decrease or increase in appetite.
- Vomiting.
- Change in bowel movements (such as diarrhea, or black, tarry or bloody stools).
- Change in behavior (such as decreased or increased activity level, incoordination, seizure, or aggression).
- Yellowing of gums, skin, or whites of the eyes (jaundice).
- Change in drinking habits (frequency or amount consumed).
- Change in urination habits (frequency, color, or smell).
- Change in skin (redness, scabs, or scratching).
- Unexpected weight loss.

It is important to stop the medication and contact your veterinarian immediately if you think your dog has a medical problem or side effect while taking PREVICOX tablets. If you have additional questions about possible side effects, talk with your veterinarian or call 1-877-217-3543.

Can PREVICOX be given with other medications?

PREVICOX should not be given with other NSAIDs (for example, aspirin, carprofen, etodolac, deracoxib, meloxicam, or tepoxalin) or corticosteroids (for example, prednisone, cortisone, dexamethasone, or triamcinolone).

Tell your veterinarian about all medications that you have given your dog in the past, and any medications you are planning to give with PREVICOX tablets. This should include other medicines that you can get without a prescription or any dietary supplements. Your veterinarian may want to check that all of your dog's medicines can be given together.

What do I do in case my dog eats more than the prescribed amount of PREVICOX?

Consult your veterinarian immediately if your dog eats more than the prescribed amount of PREVICOX.

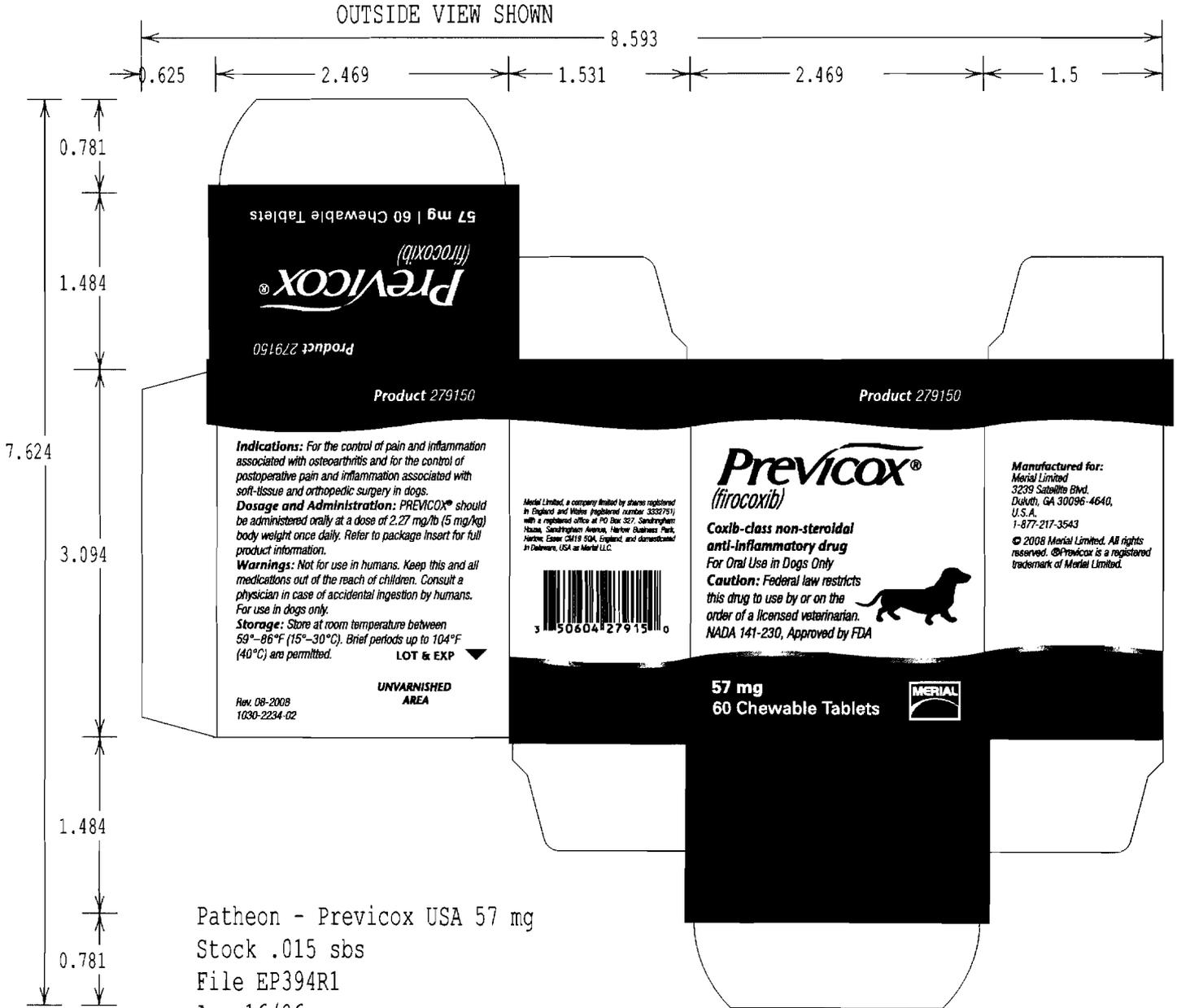
What else should I know about PREVICOX?

- This sheet provides a summary of information about PREVICOX tablets. If you have any questions or concerns about PREVICOX, osteoarthritis pain, or postoperative pain following soft-tissue and orthopedic surgery, talk with your veterinarian.
- As with all prescribed medicines, PREVICOX tablets should only be given to the dog for which they were prescribed. They should be given to your dog only for the condition for which they were prescribed, at the prescribed dose.
- It is important to periodically discuss your dog's response to PREVICOX tablets. Your veterinarian will determine if your dog is responding as expected and if your dog should continue receiving PREVICOX tablets.

For technical assistance or to report suspected adverse reactions, call 1-877-217-3543.

MADA 141-230 Approved by FDA
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PREVICOX is a registered trademark of Merial Limited.

N-141230-S-0036
 Carton Labels: 57 mg - 60 tablets



Patheon - Previcox USA 57 mg
 Stock .015 sbs
 File EP394R1
 Aug 16/06

N-141230-S-0036
Carton Labels: 227 mg - 60 tablets



N-141230-S-0036

Carton Labels: 57 mg - 30 tablets



57 mg Chewable Tablets *Previcox* (firocoxib)

Previcox[®] (firocoxib)
 Product 279120

Indications: For the control of pain and inflammation associated with osteoarthritis and for the control of postoperative pain and inflammation associated with soft-tissue and orthopedic surgery in dogs.

Dose and Administration: PREVICOX[®] should be administered orally at a dose of 2.27 mg/kg (5 mg/kg body weight) once daily. Refer to package insert for full product information.

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

For use in dogs only.

Storage: Store at room temperature between 59°-86° F (15°-30° C). Brief periods up to 104° F (40° C) are permitted.

Manufactured for:
 Merial Limited, 3029 Sableline Blvd., Duluth, GA 30096-4640, U.S.A.
 1-877-271-3543
 © 2006 Merial Limited. All rights reserved. PREVICOX is a registered trademark of Merial Limited.

Merial Limited, a company limited by shares registered in England and Wales (registered number 0232751) with a registered office at PO Box 207, Southampton Road, Southampton, Hampshire, H9 1RN, United Kingdom. Merial Limited is a subsidiary of Merial, Inc., a company limited by shares registered in Delaware, USA (Merial LLC).
 1025 1783-07 Rev. 08 2006

57 mg 30 Chewable Tablets

Previcox[®] (firocoxib)

Previcox[®] (firocoxib)



Coxib-class non-steroidal anti-inflammatory drug
 For Oral Use in Dogs Only. Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.
 NADA 141-230, Approved by FDA

57 mg | 30 Chewable Tablets



57 mg 30 Chewable Tablets

Previcox[®] (firocoxib)



PATHRON BAMP CODE

Lot & Exp

57 mg Chewable Tablets

141230-S-0036

arton Labels: 57 mg - 10 tablets



N-141230-S-0036
Carton Labels: 227 mg - 10 tablets



Merial Limited, a company limited by shares registered in England and Wales, registered number 3332751, with a registered office at Business Park, Essor, CM19 5DA, England, and incorporated in Denmark, USA as Merial LLC.
1039 1726 07
Rev. 08-2008

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1-877-217-3643

Merial Limited, 3739 Satellite Blvd., Duluth, GA 30096-4640, U.S.A.

Manufactured for:

Store at room temperature between 59°-86° F (15°-30° C). Brief periods up to 104° F (40° C) are permitted.

Storage:

Not for use in humans. Keep this and all medications out of the reach of children. Consult a physician in case of accidental ingestion by humans. For use in dogs only.

Warnings:

PREVICOX® should be administered orally at a dose of 2.27 mg/lb (5 mg/kg) body weight once daily. Refer to package insert for full product information.

Dosage and Administration:

For the control of pain and inflammation associated with osteoarthritis and for the control of postoperative pain and inflammation associated with soft-tissue and orthopedic surgery in dogs.

Indications:

Product 279170

Previcox®
(firocoxib)

10
Chewable
Tablets

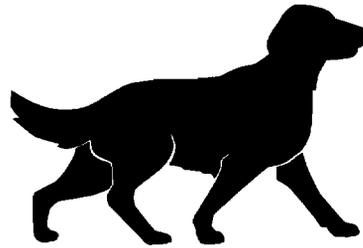
Previcox®
(firocoxib)

10
Chewable
Tablets

Previcox®
(firocoxib)

Lot & Exp

Previcox®
(firocoxib)



Coxib-class non-steroidal anti-inflammatory drug
For Oral Use in Dogs Only. **Caution:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.
NADA 141-230, Approved by FDA.

PLACE PATHFON GMP CODE

10
Chewable
Tablets

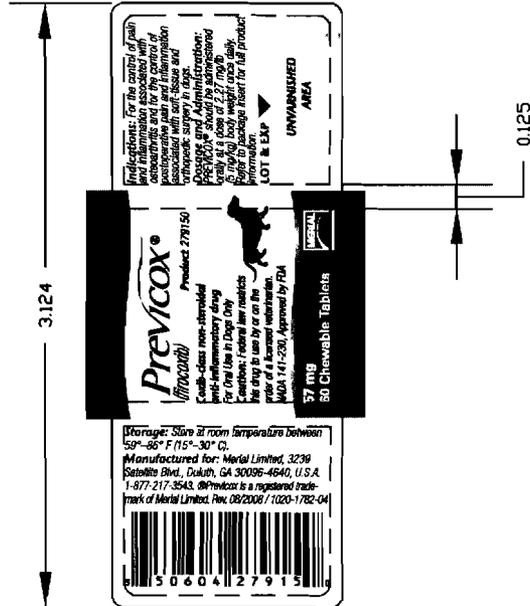


10
Chewable
Tablets

Previcox®
(firocoxib)

141230-S-0036

Bottle Labels: 57 mg - 60 tablets



N-141230-S-0036

Bottle Labels: 227 mg - 60 tablets



Previcox®
(firocoxib)

Chewable Tablets 57 mg ◯

Not for use in humans. Keep this and all drugs out of the reach of children.
Consult a physician in case of accidental ingestion by humans.

For use in dogs only.

Store at room temperature between 59° and 86°F (15°– 30°C).

Merial Limited, 3239 Satellite Blvd., Duluth, GA 30096-4640, U.S.A.



1077-1749-02
Rev.11-2006



◀ LOT & EXP

1-141230-S-0036
Blister Labels: 57 mg - 10 tablets

LOT & EXP	Previcox[®] <i>(firocoxib)</i>				
	Chewable Tablets 227 mg				
	Not for use in humans. Keep this and all drugs out of the reach of children. Consult a physician in case of accidental ingestion by humans. For use in dogs only.				
	Store at room temperature between 59° and 86°F (15° – 30°C).				
	Merial Limited, 3239 Satellite Blvd., Duluth, GA 30096-4640, U.S.A.				 1077-1751-03 Rev. 11-2006

N-141230-S-0036
Blister Labels: 227 mg - 10 tablets

N-141230-S-0036
Display Cartons: 57 mg

8.260417

Previcox[®]
(firocoxib) 57 mg Chewable Tablets



1032-1729-01
Rev. 11-2006



Previcox[®]
(firocoxib) 57 mg Chewable Tablets

Previcox[®]
(firocoxib) 57 mg Chewable Tablets



57 mg Chewable Tablets



8.5625

N-141230-S-0036
Display Cartons: 227 mg

10³/₂



Previcox[®]
(firocoxib) 227 mg Chewable Tablets



1032-1731-01
Rev. 11-2006

Previcox[®]
(firocoxib) 227 mg Chewable Tablets



Previcox[®]
(firocoxib) 227 mg Chewable Tablets

