

**ANNEX I**  
**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Previcox 57 mg chewable tablets for dogs  
Previcox 227 mg chewable tablets for dogs

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

### Active substance:

Firocoxib	57 mg
Firocoxib	227 mg

### Excipients:

Iron oxides (E172)  
Caramel (E150d)

For a full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Chewable tablets.  
Tan-brown, round, convex, engraved scored tablets.

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Dogs

### 4.2 Indications for use, specifying the target species

For the relief of pain and inflammation associated with osteoarthritis in dogs.  
For the relief of post-operative pain and inflammation associated with soft-tissue, orthopaedic and dental surgery in dogs.

### 4.3 Contraindications

Do not use in pregnant or lactating bitches.  
Do not use in animals less than 10 weeks of age or less than 3 kg body weight.  
Do not use in animals suffering from gastrointestinal bleeding, blood dyscrasia or haemorrhagic disorders.  
Do not use concomitantly with corticosteroids or other non-steroidal anti-inflammatory drugs (NSAIDs).

### 4.4 Special warnings

None.

### 4.5 Special precautions for use

#### Special precautions for use in animals

The recommended dose, as indicated in the dosing table, should not be exceeded.

Use in very young animals, or animals with suspected or confirmed impairment of renal, cardiac or hepatic function may involve additional risk. If such use cannot be avoided, those dogs require careful veterinary monitoring.

Avoid use in any dehydrated, hypovolaemic or hypotensive animals, as there is a potential risk of increased renal toxicity. Concurrent administration of potentially nephrotoxic drugs should be avoided. Use this product under strict veterinary monitoring where there is a risk of gastrointestinal bleeding, or if the animal previously displayed intolerance to NSAIDs. Renal and/or hepatic disorders have been reported in very rare cases in dogs administered the recommended treatment dose. It is possible that a proportion of such cases had sub-clinical renal or hepatic disease prior to the commencement of therapy. Therefore, appropriate laboratory testing to establish baseline renal or hepatic biochemistry parameters is recommended prior to and periodically during administration.

The treatment should be discontinued if any of these signs are observed: repeated diarrhoea, vomiting, faecal occult blood, sudden weight loss, anorexia, lethargy, degradation of renal or hepatic biochemistry parameters.

#### Special precautions to be taken by the person administering the veterinary medicinal product to animals

Wash hands after use of the product.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Return halved tablets to the blister and keep out of the reach of children.

#### **4.6 Adverse reactions (frequency and seriousness)\***

Emesis and diarrhoea have occasionally been reported. These reactions are generally of a transitory nature and are reversible when the treatment is stopped. Renal and/or hepatic disorders have been reported in very rare cases in dogs administered the recommended treatment dose. Rarely, nervous system disorders have been reported in treated dogs.

If adverse reactions like vomiting, repeated diarrhoea, faecal occult blood, sudden weight loss, anorexia, lethargy, degradation of renal or hepatic biochemistry parameters occur, use of the product should be stopped and the advice of a veterinarian should be sought. As with other NSAIDs, serious adverse effects can occur and, in very rare cases, may be fatal.

\*The frequency of possible adverse effects is defined using the following convention:

Rare (affects 1 to 10 animals in 10,000)

Very rare (affects less than 1 animal in 10,000)

#### **4.7 Use during pregnancy, lactation or lay**

Do not use in pregnant or lactating bitches.

Laboratory studies in rabbits have shown evidence of maternotoxic and foetotoxic effects at dose rates approximating the recommended treatment dose for the dog.

#### **4.8 Interaction with other medicinal products and other forms of interaction**

Pre-treatment with other anti-inflammatory substances may result in additional or increased adverse effects and accordingly a treatment-free period with such drugs should be observed for at least 24 hours before the commencement of treatment with Previcox. The treatment-free period, however, should take into account the pharmacokinetic properties of the products used previously.

Previcox must not be administered in conjunction with other NSAIDs or glucocorticosteroids.

Gastrointestinal tract ulceration may be exacerbated by corticosteroids in animals given non-steroidal anti-inflammatory drugs.

Concomitant treatment with molecules displaying action on renal flow, e.g. diuretics or Angiotensin Converting Enzyme (ACE) inhibitors, should be subject to clinical monitoring. Concurrent administration of potentially nephrotoxic drugs should be avoided as there might be an increased risk of renal toxicity. As anaesthetic drugs may affect renal perfusion, the use of parenteral fluid therapy during surgery should be considered to decrease potential renal complications when using NSAIDs peri-operatively.

Concurrent use of other active substances that have a high degree of protein binding may compete with firocoxib for binding and thus lead to toxic effects.

#### 4.9 Amounts to be administered and administration route

Oral use.

##### Osteoarthritis:

Administer 5 mg per kg bodyweight once daily as presented in the table below.

Tablets can be administered with or without food.

Duration of treatment will be dependent on the response observed. As field studies were limited to 90 days, longer-term treatment should be considered carefully and regular monitoring undertaken by the veterinarian.

##### Relief of post-operative pain:

Administer 5 mg per kg bodyweight once daily as presented in the table below for up to 3 days as needed, starting approximately 2 hours prior to surgery.

Following orthopaedic surgery and depending on the response observed, treatment using the same daily dosing schedule may be continued after the first 3 days, upon judgement of the attending veterinarian.

Body weight (kg)	Number of chewable tablets by size		mg/kg range
	57 mg	227 mg	
3.0 – 5.5	0.5		5.2 – 9.5
5.6 – 10	1		5.7 – 10.2
10.1 – 15	1.5		5.7 – 8.5
15.1 – 22		0.5	5.2 – 7.5
22.1 – 45		1	5.0 – 10.3
45.1 – 68		1.5	5.0 – 7.5
68.1 – 90		2	5.0 – 6.7

#### 4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

In dogs ten weeks of age at the start of treatment at dose rates equal or greater to 25 mg/kg/day (5 times the recommended dose) for three months, the following signs of toxicity were observed: bodyweight loss, poor appetite, changes in the liver (accumulation of lipid), brain (vacuolisation), duodenum (ulcers) and death. At dose rates equal or greater to 15 mg/kg/day (3 times the recommended dose) for six months, similar clinical signs were observed, albeit that the severity and frequency were less and duodenal ulcers were absent.

In those target animal safety studies, clinical signs of toxicity were reversible in some dogs following cessation of therapy.

In dogs seven months of age at the start of treatment at dose rates greater than or equal to 25 mg/kg/day (5 times the recommended dose) for six months, gastrointestinal adverse effects, i.e. vomiting were observed.

Overdose studies were not conducted in animals over 14 months of age.

If clinical signs of overdosing are observed, discontinue treatment.

#### **4.11 Withdrawal period(s)**

Not applicable.

### **5. PHARMACOLOGICAL PROPERTIES**

Pharmacotherapeutic group: Anti-inflammatory and anti-rheumatic products, non-steroids.  
ATCvet code: QM01AH90.

#### **5.1 Pharmacodynamic properties**

Firocoxib is a non-steroidal anti-inflammatory drug (NSAID) belonging to the Coxib group, which acts by selective inhibition of cyclooxygenase-2 (COX-2) – mediated prostaglandin synthesis. Cyclooxygenase is responsible for generation of prostaglandins. COX-2 is the isoform of the enzyme that has been shown to be induced by pro-inflammatory stimuli and has been postulated to be primarily responsible for the synthesis of prostanoid mediators of pain, inflammation, and fever. Coxibs therefore display analgesic, anti-inflammatory and antipyretic properties. COX-2 is also thought to be involved in ovulation, implantation and closure of the *ductus arteriosus*, and central nervous system functions (fever induction, pain perception and cognitive function). In *in-vitro* canine whole blood assays, firocoxib exhibits approximately 380-fold selectivity for COX-2 over COX-1. The concentration of firocoxib required to inhibit 50 % of the COX-2 enzyme (i.e., the IC<sub>50</sub>) is 0.16 (± 0.05) µM, whereas the IC<sub>50</sub> for COX-1 is 56 (± 7) µM.

#### **5.2 Pharmacokinetic particulars**

Following oral administration in dogs at the recommended dose of 5 mg per kg of bodyweight, firocoxib is rapidly absorbed and the time to maximal concentration (T<sub>max</sub>) is 1.25 (± 0.85) hours. The peak concentration (C<sub>max</sub>) is 0.52 (± 0.22) µg/ml (equivalent to approximately 1.5 µM), area under the curve (AUC 0-24) is 4.63 (±1.91) µg x hr/ml, and oral bioavailability is 36.9 (± 20.4) percent. The elimination half-life (t<sub>1/2</sub>) is 7.59 (± 1.53) hours. Firocoxib is approximately 96 % bound to plasma proteins. Following multiple oral administrations, the steady state is reached by the third daily dose. Firocoxib is metabolised predominantly by dealkylation and glucuronidation in the liver. Elimination is principally in the bile and gastrointestinal tract.

### **6. PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Lactose Monohydrate  
Microcrystalline Cellulose  
Chartor Hickory Smoke Flavour  
Hydroxypropyl Cellulose  
Croscarmellose Sodium  
Magnesium Stearate  
Caramel (E150d)  
Silica, colloidal anhydrous  
Iron Oxides (E172)

#### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale: 4 years.

Half tablets should be returned to the original market container and may be stored for up to 7 days.

### **6.4 Special precautions for storage**

Do not store above 30 °C.

Store in the original package.

### **6.5 Nature and composition of immediate packaging**

Previcox tablets are supplied in blisters (transparent PVC /aluminium foil) or in 30 ml or 100 ml high density polyethylene bottles (with polypropylene closure).

The chewable tablets (57 mg or 227 mg) are available in the following pack sizes:

- 1 cardboard box containing 10 tablets in one blister
- 1 cardboard box containing 30 tablets in three blisters
- 1 cardboard box containing 180 tablets in eighteen blisters
- 1 cardboard box containing 60 tablets in one bottle

Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

## **7. MARKETING AUTHORISATION HOLDER**

MERIAL

29 avenue Tony Garnier

69007 Lyon

France

## **8. MARKETING AUTHORISATION NUMBER(S)**

EU/2/04/045/001-006

EU/2/04/045/008-009

## **9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

13/09/2004

## **10. DATE OF REVISION OF THE TEXT**

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency <http://www.ema.europa.eu>.

**PROHIBITION OF SALE, SUPPLY AND/OR USE**

Not applicable.

## **ANNEX II**

- A. MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE**
- B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE**
- C. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION WITH REGARD TO SAFE AND EFFECTIVE USE**
- D. STATEMENT OF THE MRLs**



**A. MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE**

Name and address of the manufacturer responsible for batch release

MERIAL S.A.S.  
4 Chemin de Calquet  
31000 Toulouse  
France

**B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE**

To be supplied only on veterinary prescription.

**C. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE PRODUCT**

Not applicable.

**D. STATEMENT OF THE MRLs**

Not Applicable

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Carton Box labelling**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Previcox 57 mg chewable tablets for dogs

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Firocoxib 57 mg

**3. PHARMACEUTICAL FORM**

Chewable tablet

**4. PACKAGE SIZE**

10 tablets  
30 tablets  
60 tablets  
180 tablets

**5. TARGET SPECIES**

Dogs

**6. INDICATION(S)**

Pain and inflammation associated with osteoarthritis.  
Peri-operative pain management.

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Oral use.  
Administer 5 mg per kg bodyweight once daily.

**8. WITHDRAWAL PERIOD**

Not applicable

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use.

**10. EXPIRY DATE**

EXP {month/year}

Half tablets should be returned to the original market container and may be stored for up to 7 days.

**11. SPECIAL STORAGE CONDITIONS**

Do not store above 30 °C.

**12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Read the package leaflet before use.

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable**

For animal treatment only - to be supplied only on veterinary prescription.

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

Keep out of the reach and sight of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

MERIAL, 29 avenue Tony Garnier, 69007 Lyon, France

**16. MARKETING AUTHORISATION NUMBER(S)**

EU/2/04/045/001 10 tablets

EU/2/04/045/002 30 tablets

EU/2/04/045/005 180 tablets

EU/2/04/045/008 60 tablets

**17. MANUFACTURER’S BATCH NUMBER**

Lot

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Carton Box labelling**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Previcox 227 mg chewable tablets for dogs

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Firocoxib 227 mg

**3. PHARMACEUTICAL FORM**

Chewable tablet

**4. PACKAGE SIZE**

10 tablets  
30 tablets  
60 tablets  
180 tablets

**5. TARGET SPECIES**

Dogs

**6. INDICATION(S)**

Pain and inflammation associated with osteoarthritis.  
Peri-operative pain management.

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Oral use.  
Administer 5 mg per kg bodyweight once daily.

**8. WITHDRAWAL PERIOD**

Not applicable

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use.

**10. EXPIRY DATE**

EXP {month/year}

Half tablets should be returned to the original market container and may be stored for up to 7 days.

**11. SPECIAL STORAGE CONDITIONS**

Do not store above 30 °C.

**12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Read the package leaflet before use.

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable**

For animal treatment only - to be supplied only on veterinary prescription.

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

Keep out of the reach and sight of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

MERIAL, 29 avenue Tony Garnier, 69007 Lyon, France

**16. MARKETING AUTHORISATION NUMBER(S)**

EU/2/04/045/003 10 tablets

EU/2/04/045/004 30 tablets

EU/2/04/045/006 180 tablets

EU/2/04/045/009 60 tablets

**17. MANUFACTURER’S BATCH NUMBER**

Lot

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

{NATURE/TYPE}

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Previcox 57 mg chewable tablets  
Firocoxib

**2. NAME OF THE MARKETING AUTHORISATION HOLDER**

MERIAL

**3. EXPIRY DATE**

EXP {month/year}

**4. BATCH NUMBER**

Lot



**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

{NATURE/TYPE}

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Previcox 227 mg chewable tablets  
Firocoxib

**2. NAME OF THE MARKETING AUTHORISATION HOLDER**

MERIAL

**3. EXPIRY DATE**

EXP {month/year}

**4. BATCH NUMBER**

Lot

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**Bottle label**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Previcox 57 mg chewable tablets for dogs  
Previcox 227 mg chewable tablets for dogs

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

Firocoxib 57 mg  
Firocoxib 227 mg

**3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

60 tablets

**4. ROUTE(S) OF ADMINISTRATION**

Oral use

**5. WITHDRAWAL PERIOD**

Not applicable

**6. BATCH NUMBER**

Lot

**7. EXPIRY DATE**

EXP {month/year}

**8. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

**B. PACKAGE LEAFLET**

**PACKAGE LEAFLET**  
**Previcox 57 mg chewable tablets for dogs**  
**Previcox 227 mg chewable tablets for dogs**

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

Marketing authorisation holder:

MERIAL, 29 avenue Tony Garnier, 69007 Lyon, France

Manufacturer for the batch release:

MERIAL, 4 Chemin du Calquet, 31000 Toulouse, France

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Previcox 57 mg chewable tablets for dogs

Previcox 227 mg chewable tablets for dogs

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

Each tablet contains:

Firocoxib                      57 mg

Firocoxib                      227 mg

Iron oxides (E172)

Caramel (E150d)

**4. INDICATION(S)**

For the relief of pain and inflammation associated with osteoarthritis in dogs.

For the relief of post-operative pain and inflammation associated with soft-tissue, orthopaedic and dental surgery in dogs.

**5. CONTRAINDICATIONS**

Do not use in pregnant or lactating bitches.

Laboratory studies in rabbits have shown evidence of maternotoxic and foetotoxic effects at dose rates approximating the recommended treatment dose for the dog.

Do not use in animals less than 10 weeks of age or less than 3 kg bodyweight.

Do not use in animals suffering from gastrointestinal bleeding, blood dyscrasia or haemorrhagic disorders.

Do not use concomitantly with corticosteroids or other non-steroidal anti-inflammatory drugs (NSAIDs).

**6. ADVERSE REACTIONS\***

Emesis and diarrhoea have occasionally been reported. These reactions are generally of a transitory nature and are reversible when the treatment is stopped. Renal and/or hepatic disorders have been reported in very rare cases in dogs administered the recommended treatment dose. Rarely, nervous system disorders have been reported in treated dogs.

If adverse reactions like vomiting, repeated diarrhoea, faecal occult blood, sudden weight loss, anorexia, lethargy, degradation of renal or hepatic biochemistry parameters occur, use of the product should be stopped and the advice of a veterinarian should be sought. As with other NSAIDs, serious adverse effects can occur and, in very rare cases, may be fatal.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

\*The frequency of possible adverse effects is defined using the following convention:

Rare (affects 1 to 10 animals in 10,000)

Very rare (affects less than 1 animal in 10,000)

## 7. TARGET SPECIES

Dogs.

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

5 mg/kg once daily.

For the reduction of post-operative pain and inflammation, the animals can be dosed starting approximately 2 hours before surgery for up to 3 consecutive days as needed. Following orthopaedic surgery and depending on the response observed, treatment using the same daily dosing schedule may be continued after the first 3 days, upon judgement of the attending veterinarian.

For oral use as per table below.

Body weight (kg)	Number of chewable tablets by size	
	57 mg	227 mg
3.0 – 5.5	0.5	
5.6 – 10	1	
10.1 – 15	1.5	
15.1 – 22		0.5
22.1 – 45		1
45.1 – 68		1.5
68.1 – 90		2

## 9. ADVICE ON CORRECT ADMINISTRATION

Tablets can be administered with or without food. Do not exceed the recommended dose.

Duration of treatment will be dependent on the response observed. As field studies were limited to 90 days, longer-term treatment should be considered carefully and regular monitoring undertaken by the veterinarian.

## 10. WITHDRAWAL PERIOD

Not applicable

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Do not store above 30 °C.

In order to protect from moisture, store in the original package.

Do not use after the expiry date stated on the label.

Half tablets should be returned to the original market container and may be stored for up to 7 days.

## **12. SPECIAL WARNING(S)**

Use in very young animals, or animals with suspected or confirmed impairment of renal, cardiac or hepatic function may involve additional risk. If such use cannot be avoided, those dogs require careful veterinary monitoring. Appropriate laboratory testing is recommended prior to treatment in order to detect subclinical (asymptomatic) renal or hepatic disorders that may predispose to adverse effects. Avoid use in any dehydrated, hypovolaemic or hypotensive animals, as there is a risk of increased renal toxicity. Concurrent administration of potentially nephrotoxic drugs should be avoided.

Use this product under strict veterinary monitoring where there is a risk of gastro-intestinal bleeding, or if the animal previously displayed intolerance to NSAIDs. The treatment should be discontinued if any of these signs are observed: repeated diarrhoea, vomiting, faecal occult blood, sudden weight loss, anorexia, lethargy, degradation of renal or hepatic biochemistry parameters.

As anaesthetic drugs may affect renal perfusion, the use of parenteral fluids during surgery should be considered to decrease potential renal complications when using NSAIDs peri-operatively.

Pre-treatment with other anti-inflammatory substances may result in additional or increased adverse effects and accordingly a treatment-free period with such drugs should be observed for at least 24 hours before the commencement of treatment with Previcox. The treatment-free period, however, should take into account the pharmacokinetic properties of the products used previously.

Previcox must not be administered in conjunction with other NSAIDs or glucocorticosteroids. Gastrointestinal tract ulceration may be exacerbated by corticosteroids in animals given non-steroidal anti-inflammatory drugs.

Concomitant treatment with molecules displaying action on renal flow, e.g. diuretics or Angiotensin Converting Enzyme (ACE) inhibitors, should be subject to clinical monitoring. Concurrent administration of potentially nephrotoxic drugs should be avoided as there might be an increased risk for renal toxicity. Concurrent use of other active substances that have a high degree of protein binding may compete with firocoxib for binding and thus lead to toxic effects.

In case of accidental ingestion, seek medical advice immediately and show the package insert or the label to the physician.

Wash hands after use of the product.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

## **14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

Detailed information on this product is available on the website of the European Medicines Agency <http://www.ema.europa.eu>.

## 15. OTHER INFORMATION

Mode of action:

Firocoxib is a non-steroidal anti-inflammatory drug (NSAID) that acts by selective inhibition of cyclooxygenase-2 (COX-2) – mediated prostaglandin synthesis. COX-2 is the isoform of the enzyme that has been postulated to be primarily responsible for the synthesis of prostanoid mediators of pain, inflammation, and fever. In *in-vitro* canine whole blood assays, firocoxib exhibited approximately 380-fold selectivity for COX-2 over COX-1.

Previcox Chewable tablets are scored to facilitate accurate dosing and contain caramel and smoke flavours to facilitate administration to dogs. Not all pack sizes may be marketed.

The chewable tablets (57 mg or 227 mg) are available in the following pack sizes:

- 1 cardboard box containing 10 tablets in one blister
- 1 cardboard box containing 30 tablets in three blisters
- 1 cardboard box containing 180 tablets in eighteen blisters
- 1 cardboard box containing 60 tablets in one bottle