**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 chewable tablet contains:

**Active substance:**
Firocoxib ..... 57 mg
or
Firocoxib ..... 227 mg

**Excipients:**

| **Qualitative composition of excipients and other constituents** |
|---|
| Lactose monohydrate |
| Microcrystalline cellulose |
| Chartor hickory smoke flavour |
| Hydroxypropylcellulose |
| Croscarmellose sodium |
| Magnesium stearate |
| Caramel (E150d) |
| Silica, colloidal anhydrous |
| Yellow iron oxide (E172) |
| Red iron oxide (E172) |

Tan-brown, round, convex, chewable tablets with a cross-shaped break line on one side. The chewable tablets can be divided into 2 or 4 equal parts.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Dogs.

### 3.2 Indications for use for each 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.

### 3.3 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).

### 3.4 Special warnings

None.

### 3.5 Special precautions for use

Special precautions for safe use in the target species:

The recommended dose, see section 3.9, 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 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.
Divided tablets should be returned to the original package.

Special precautions for the protection of the environment:

Not applicable.

### 3.6 Adverse events

Dogs:

| | |
|---|---|
| Uncommon (1 to 10 animals / 1,000 animals treated): | Vomiting[1] and diarrhoea.[1] |
| Rare (1 to 10 animals / 10,000 animals treated): | Nervous system disorders |
| Very rare (<1 animal / 10,000 animals treated, including isolated reports): | Hepatic disorders and Renal disorders. |

[1] Generally of a transitory nature and reversible when the treatment is stopped.

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.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

### 3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

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.

### 3.8 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 the veterinary medicinal product. The treatment-free period, however, should take into account the pharmacokinetic properties of the products used previously.

The veterinary medicinal product 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.

### 3.9 Administration routes and dosage

Oral use.

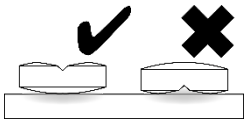
Osteoarthritis:
Administer 5 mg per kg bodyweight once daily as presented in the table below.
Tablets can be administered with or without food.
Duration of treatment will be dependent on the response observed. As field studies were limited to 90 days, longer-term treatment should be considered carefully 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.

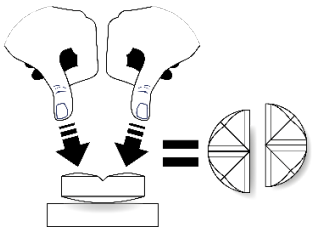
Following orthopaedic surgery and depending on the response observed, treatment using the same daily dosing schedule may be continued after the first 3 days, upon judgement of the attending veterinarian.

| 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 – 7.5 | 0.75 | | 5.7 – 7.6 |
| 7.6 – 10 | 1 | 0.25 | 5.7 – 7.5 |
| 10.1 – 13 | 1.25 | | 5.5 – 7.1 |
| 13.1 – 16 | 1.5 | | 5.3 – 6.5 |
| 16.1 – 18.5 | 1.75 | | 5.4 – 6.2 |
| 18.6 – 22.5 | | 0.5 | 5.0 – 6.1 |
| 22.6 – 34 | | 0.75 | 5.0 – 7.5 |
| 34.1 – 45 | | 1 | 5.0 – 6.7 |
| 45.1 – 56 | | 1.25 | 5.1 – 6.3 |
| 56.1 – 68 | | 1.5 | 5.0 – 6.1 |
| 68.1 – 79 | | 1.75 | 5.0 – 5.8 |
| 79.1 – 90 | | 2 | 5.0 – 5.7 |

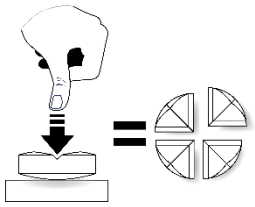
Tablets can be divided into 2 or 4 equal parts to enable accurate dosing.



Place the tablet on a flat surface, with its scored side facing up and the convex (rounded) side facing the surface.



To split into 2 equal parts:
Press your thumbs down on both sides of the tablet.



To split into 4 equal parts:
Press your thumb down in the middle of the tablet.

### 3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

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

Not applicable.

### 3.12 Withdrawal periods

Not applicable.

## 4. PHARMACOLOGICAL INFORMATION

### 4.1 ATCvet code: QM01AH90.

### 4.2 Pharmacodynamics

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 $IC_{50}$) is 0.16 (± 0.05) µM, whereas the $IC_{50}$ for COX-1 is 56 (± 7) µM.

### 4.3 Pharmacokinetics

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 ($T_{max}$) is 1.25 (± 0.85) hours. The peak concentration ($C_{max}$) 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 ($t_{½}$) 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.

## 5. PHARMACEUTICAL PARTICULARS

### 5.1 Major incompatibilities

Not applicable.

### 5.2 Shelf life

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

Divided tablets may be stored for up to 1 month in the original package.

### 5.3 Special precautions for storage

Do not store above 30 °C.
Store in the original package.

### 5.4 Nature and composition of immediate packaging

Previcox chewable 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 1 blister of 10 tablets (10 tablets).
- 1 cardboard box containing 3 blisters of 10 tablets (30 tablets).
- 1 cardboard box containing 18 blisters of 10 tablets (180 tablets).
- 1 cardboard box containing 1 bottle of 60 tablets.

Not all pack sizes may be marketed.

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

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

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

## 6. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

## 7. MARKETING AUTHORISATION NUMBER(S)

EU/2/04/045/001-006
EU/2/04/045/008-009

## 8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 13/09/2004

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

{MM/YYYY}

## 10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

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

**ANNEX II**

**OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION**

None.

**ANNEX III**

**LABELLING AND PACKAGE LEAFLET**

# A. LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Cardboard box**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Previcox 57 mg chewable tablets
Previcox 227 mg chewable tablets

## 2. STATEMENT OF ACTIVE SUBSTANCES

Firocoxib 57 mg
Firocoxib 227 mg

## 3. PACKAGE SIZE

10 [picture of a tablet]
30
60
180

## 4. TARGET SPECIES

Dogs.

## 5. INDICATIONS

## 6. ROUTES OF ADMINISTRATION

Oral use.

## 7. WITHDRAWAL PERIODS

## 8. EXPIRY DATE

Exp. {mm/yyyy}
Divided tablets may be stored for up to 1 month in the original package.

## 9. SPECIAL STORAGE PRECAUTIONS

Do not store above 30 °C.
Store in the original package.

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

Read the package leaflet before use.

## 11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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

Keep out of the sight and reach of children.

## 13. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

## 14. MARKETING AUTHORISATION NUMBERS

EU/2/04/045/001 10 tablets (57 mg)
EU/2/04/045/002 30 tablets (57 mg)
EU/2/04/045/003 10 tablets (227 mg)
EU/2/04/045/004 30 tablets (227 mg)
EU/2/04/045/005 180 tablets (57 mg)
EU/2/04/045/006 180 tablets (227 mg)
EU/2/04/045/008 60 tablets (57 mg)
EU/2/04/045/009 60 tablets (227 mg)

## 15. BATCH NUMBER

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

**Bottle of 100 ml**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Previcox 227 mg chewable tablets

## 2. STATEMENT OF ACTIVE SUBSTANCES

Firocoxib ..... 227 mg

60 [picture of a tablet]

## 3. TARGET SPECIES

Dogs.

## 4. ROUTES OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

## 5. WITHDRAWAL PERIODS

## 6. EXPIRY DATE

Exp. {mm/yyyy}
Divided tablets may be stored for up to 1 month in the original package.

## 7. SPECIAL STORAGE PRECAUTIONS

Do not store above 30 °C.
Store in the original package.

## 8. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

## 9. BATCH NUMBER

Lot {number}

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

**Blister foil**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Previcox

## 2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Firocoxib 57 mg
Firocoxib 227 mg

## 3. BATCH NUMBER

Lot {number}

## 4. EXPIRY DATE

Exp. {mm/yyyy}

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

**Bottle of 30 ml**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Previcox

## 2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Firocoxib 57 mg

60 [picture of a tablet]

## 3. BATCH NUMBER

Lot {number}

## 4. EXPIRY DATE

Exp. {mm/yyyy}

**B. PACKAGE LEAFLET**

# PACKAGE LEAFLET

## 1. Name of the veterinary medicinal product

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

## 2. Composition

Each chewable tablet contains:

**Active substance:**
Firocoxib ..... 57 mg
or
Firocoxib ..... 227 mg

Tan-brown, round, convex, chewable tablets with a cross-shaped break line on one side. The chewable tablets can be divided into 2 or 4 equal parts.

## 3. Target species

Dogs.

## 4. Indications for use

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.
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. Special warnings

Special precautions for safe use in the target species:

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 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.

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.

Divided tablets should be returned to the original package.

Pregnancy and lactation:

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.

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 the veterinary medicinal product. The treatment-free period, however, should take into account the pharmacokinetic properties of the products used previously.

The veterinary medicinal product 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. 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.

Overdose:

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.

## 7. Adverse events

**Uncommon (1 to 10 animals / 1,000 animals treated):**
Vomiting[1] and diarrhoea[1].

**Rare (1 to 10 animals / 10,000 animals treated):**
Nervous system disorders.

**Very rare (<1 animal / 10,000 animals treated, including isolated reports):**
Hepatic disorders and Renal disorders.

[1] Generally of a transitory nature and reversible when the treatment is stopped.

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.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

## 8. Dosage for each species, routes and method of administration

5 mg/kg once daily.

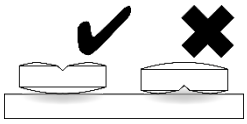
For the reduction of post-operative pain and inflammation, the animals can be dosed starting approximately 2 hours before surgery for up to 3 consecutive days as needed. Following orthopaedic surgery and depending on the response observed, treatment using the same daily dosing schedule may be continued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

For oral use as per table below.

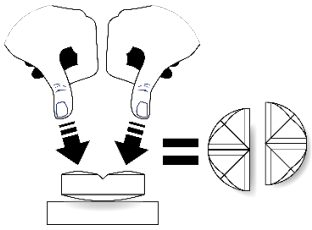
| Body weight (kg) | Number of chewable tablets by size | | mg/kg range |
|---|---|---|---|
| | 57 mg | 227 mg | |
| 3.0 – 5.5 | 0.5 | | 5.2 – 9.5 |
| 5.6 – 7.5 | 0.75 | | 5.7 – 7.6 |
| 7.6 – 10 | 1 | 0.25 | 5.7 – 7.5 |
| 10.1 – 13 | 1.25 | | 5.5 – 7.1 |
| 13.1 – 16 | 1.5 | | 5.3 – 6.5 |
| 16.1 – 18.5 | 1.75 | | 5.4 – 6.2 |
| 18.6 – 22.5 | | 0.5 | 5.0 – 6.1 |
| 22.6 – 34 | | 0.75 | 5.0 – 7.5 |
| 34.1 – 45 | | 1 | 5.0 – 6.7 |
| 45.1 – 56 | | 1.25 | 5.1 – 6.3 |
| 56.1 – 68 | | 1.5 | 5.0 – 6.1 |
| 68.1 – 79 | | 1.75 | 5.0 – 5.8 |

| | | | |
|---|---|---|---|
| 79.1 – 90 | | 2 | 5.0 – 5.7 |

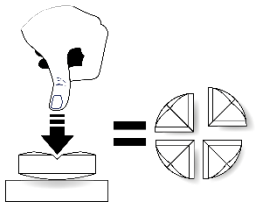
Tablets can be divided into 2 or 4 equal parts to enable accurate dosing.



Place the tablet on a flat surface, with its scored side facing up and the convex (rounded) side facing the surface.



To split in 2 equal parts:
Press your thumbs down on both sides of the tablet.



To split into 4 equal parts:
Press your thumb down in the middle of the tablet.

## 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 periods

Not applicable.

## 11. Special storage precautions

Keep out of the sight and reach of children.
Do not store above 30 °C.
Store in the original package.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton after Exp. The expiry date refers to the last day of that month.
Divided tablets may be stored for up to 1 month in the original package.

## 12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

## 13. Classification of veterinary medicinal products

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

## 14. Marketing authorisation numbers and pack sizes

EU/2/04/045/001-006
EU/2/04/045/008-009

The chewable tablets (57 mg or 227 mg) are available in the following pack sizes:
- 1 cardboard box containing 1 blister of 10 tablets (10 tablets).
- 1 cardboard box containing 3 blisters of 10 tablets (30 tablets).
- 1 cardboard box containing 18 blisters of 10 tablets (180 tablets).
- 1 cardboard box containing 1 bottle of 60 tablets.

Not all pack sizes may be marketed.

## 15. Date on which the package leaflet was last revised

{MM/YYYY}

## 16. Contact details

Marketing authorisation holder:
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
Germany

Manufacturer responsible for batch release:
Boehringer Ingelheim Animal Health France SCS,
4 Chemin du Calquet, 31000 Toulouse,
France

Local representatives and contact details to report suspected adverse events:

**België/Belgique/Belgien**
Boehringer Ingelheim Animal
Health Belgium SA
Avenue Arnaud Fraiteurlaan 15-23,
1050 Bruxelles/Brussel/Brüssel
Tél/Tel: + 32 2 773 34 56

**Република България**
Boehringer Ingelheim RCV GmbH & Co KG
Dr. Boehringer Gasse 5-11
A-1121 Виена, Австрия
Tel: +359 2 958 79 98

**Česká republika**
Boehringer Ingelheim spol. s r.o.
Purkyňova 2121/3
CZ - 110 00, Praha 1
Tel: +420 234 655 111

**Lietuva**
Boehringer Ingelheim RCV GmbH & Co KG
Lietuvos filialas
Dr. Boehringer Gasse 5-11
A-1121 Vīne, Austrija
Tel: +370 5 2595942

**Luxembourg/Luxemburg**
Boehringer Ingelheim Animal Health Belgium SA
Avenue Arnaud Fraiteurlaan 15-23,
1050 Bruxelles/Brussel/Brüssel
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## 17. 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.

The chewable tablets are scored to facilitate accurate dosing and contain caramel and smoke flavours to facilitate administration to dogs.