SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Previcox 227 mg chewable tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains:

Active substance:
Firocoxib 227 mg

Excipients:
Iron oxides (E172)
Caramel (E150d)

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Chewable tablets.
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.

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 for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

The recommended dose, see section 4.9, 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.

Other precautions
Not applicable.

4.6 Adverse reactions (frequency and seriousness)

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 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.

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 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.

4.9 Amount(s) to be administered and administration route

Oral use.

<u>Osteoarthritis:</u>
Administer 5 mg per kg bodyweight once daily as presented in the table below.

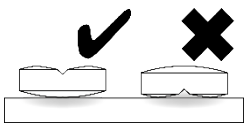
Tablets can be administered with or without food.
Duration of treatment will be dependent on the response observed. As field studies were limited to 90 days, longer-term treatment should be considered carefully and regular monitoring undertaken by the veterinarian.

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.

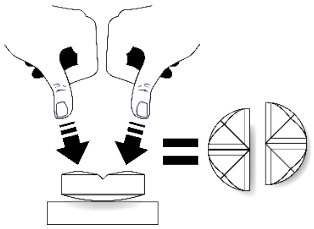
Following orthopaedic surgery and depending on the response observed, treatment using the same daily dosing schedule may be continued after the first 3 days, upon judgement of the attending veterinarian.

Body weight (kg)	Number of chewable tablets by size	mg/kg range
	227 mg	
7.6 – 10	0.25	5.7 – 7.5
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

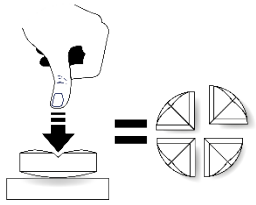
Tablets can be divided into 2 or 4 equal parts to enable accurate dosing.



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.

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 IC50) is 0.16 (± 0.05) µM, whereas the IC50 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_{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 (t½) 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 Cellulise
Chartor Hickory Smoke Flavour
Hydroxypropylcellulose
Croscarmellose Sodium
Magnesium Stearate
Caramel (E150d)
Silica, colloidal anhydrous
Yellow iron oxide (E172)
Red iron oxide (E172)

6.2 Major incompatibilities

Not applicable.

6.3 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.

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

The chewable tablets 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.

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

Medicines should not be disposed of via wastewater.

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

Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

8. MARKETING AUTHORISATION NUMBER

Vm 61700/5073

9. DATE OF FIRST AUTHORISATION

13 September 2004

10. DATE OF REVISION OF THE TEXT

January 2024

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Gavin Hall
Approved: 20 July 2024