PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Cardboard box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Previcox 57 mg chewable tablets

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Firocoxib 57 mg

3. PACKAGE SIZE

10
30
60
180

4. TARGET SPECIES

Dogs.

5. INDICATION(S)

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

Vm 04491/5045

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {bottle of 30 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Previcox

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Firocoxib 57 mg

60

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

5. ROUTE(S) OF ADMINISTRATION

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Previcox

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Firocoxib 57 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

PARTICULARS TO APPEAR ON THE 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

Excipients:
Iron oxides (E172)
Caramel (E150d)

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

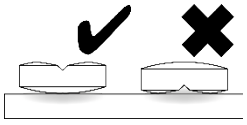
5 mg/kg once daily.

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.

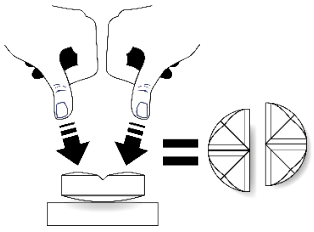
For oral use as per table below.

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

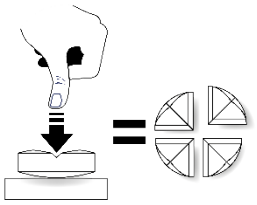
Tablets can be divided into 2 or 4 equal parts to enable accurate dosing.



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.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.
These measures should help to protect the environment. Ask your veterinary surgeon how to dispose of medicines no longer required.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

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.

Vm 04491/5044
Vm 04491/5045

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder:
Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am 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:

United Kingdom (Great Britain)
Boehringer Ingelheim Animal Health UK Ltd., United Kingdom
Tel: + 44 1344 746957

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.

POM-V
Veterinary medicinal product subject to prescription

Gavin Hall
Approved: 20 July 2024