PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARDBOARD BOX LABELLING}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Coxatab 57 mg chewable tablets

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Firocoxib 57 mg

3. PACKAGE SIZE

10 tablets
20 tablets
30 tablets
50 tablets
100 tablets
200 tablets

4. TARGET SPECIES

Dogs

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp{mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

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

CP-Pharma Handelsgesellschaft mbH

14. MARKETING AUTHORISATION NUMBERS

Vm 20916/5014

15. BATCH NUMBER

Batch

16. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

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

POM-V (Veterinary medicinal product subject to prescription).

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS {Blister foil}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Coxatab

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Firocoxib 57 mg

3. BATCH NUMBER

Batch

4. EXPIRY DATE

EXP

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Coxatab 57 mg chewable tablets for dogs

2. COMPOSITION

Each chewable tablet contains:

Active substance:
Firocoxib 57 mg

Off-white to light brown, speckled with brown spots, round and convex tablet with a cross-shaped break line on one side. The 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 cases of hypersensitivity to the active substance or to any of the excipients.
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).

6. SPECIAL WARNING(S)

Special precautions for use in animals:
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 medicines should be avoided.

Use this veterinary medicinal 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:
This product may be harmful following accidental ingestion. The target organs for toxicity in the repeat-dose toxicological studies were usually liver, brain and gastrointestinal tract.
In order to prevent children from accessing the product, tablets should be administered and stored out of their sight and reach. Halved or quartered tablets should be returned to the open blister pocket and inserted into the outer carton.
In the event of accidental ingestion of one or more tablets, seek medical advice immediately and show the package leaflet or the label to the doctor.
Laboratory studies in rats and rabbits have shown evidence that firocoxib has the potential to affect reproduction and to induce malformations in foetuses. Pregnant women or women who are intending to become pregnant should administer the product with caution.

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 medicines 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 medicines used previously.

The 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 medicines should be avoided as there might be an increased risk for renal toxicity. As anaesthetic

medicines 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 (symptoms, emergency procedures, 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.

Major Incompatibilities
Not applicable.

7. ADVERSE EVENTS

Dogs:

Uncommon (1 to 10 animals / 1,000 animals treated):	Vomiting[1], Diarrhoea[1]
Rare (1 to 10 animals / 10,000 animals treated):	Nervous system disorder
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hepatic disorder Renal disorder

[1]These reactions are generally of a transitory nature and are 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><the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system https://www.gov.uk/report-veterinary-medicine-problem.

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**	**mg/kg bw range**
	57 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	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

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**.**

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(S)

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Keep the blister strip in the outer carton This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

POM-V Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

The chewable tablets (57 mg) are available in the following pack sizes:
- Cardboard box with 10 tablets
- Cardboard box with 20 tablets
- Cardboard box with 30 tablets
- Cardboard box with 50 tablets
- Cardboard box with 100 tablets
- Cardboard box with 200 tablets

Not all pack sizes may be marketed.

Vm{number}

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

Find more product information by searching for the ‘Product Information Database’ or ‘PID’ on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

CP-Pharma Handelsgesellschaft mbH
Ostlandring 13
31303 Burgdorf
Germany
Tel.: +49 5136 60660
info@cp-pharma.de

17. OTHER INFORMATION

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.

Coxatab chewable tablets are scored to facilitate accurate dosing and contain hydrolysed chicken flavour to facilitate administration to dogs.

Approved: 08 July 2024

Gavin Hall