

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

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Coxatab 25 mg chewable tablets for dogs  
Coxatab 57 mg chewable tablets for dogs  
Coxatab 100 mg chewable tablets for dogs  
Coxatab 225 mg chewable tablets for dogs

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains:

### Active substance:

#### Coxatab 25 mg chewable tablets

Firocoxib 25 mg

#### Coxatab 57 mg chewable tablets

Firocoxib 57 mg

#### Coxatab 100 mg chewable tablets

Firocoxib 100 mg

#### Coxatab 225 mg chewable tablets

Firocoxib 225 mg

### Excipients:

Qualitative composition of excipients and other constituents
Lactose monohydrate
Microcrystalline cellulose
Hydroxypropyl cellulose
Croscarmellose sodium
Silica, colloidal hydrated
Magnesium stearate
Chicken flavour

Off-white to light brown, speckled with brown spots, round and convex chewable tablet with a cross-shaped break line on one side. The 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 cases of hypersensitivity to the active substance or to any of the excipients.
- in pregnant or lactating bitches.
- in animals less than 10 weeks of age or less than 3 kg body weight.
- in animals suffering from gastrointestinal bleeding, blood dyscrasia or haemorrhagic disorders.

### 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 medicinal products should be avoided.

Use this veterinary medicinal 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 <sup>1</sup> , Diarrhoea <sup>1</sup>
Rare	Nervous system disorder

(1 to 10 animals / 10 000 animals treated):	
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Renal disorder Hepatic disorder

<sup>1</sup> 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 veterinary medicinal products may result in additional or increased adverse effects and accordingly a treatment-free period with such veterinary medicinal products 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 veterinary medicinal 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 veterinary medicinal products should be avoided as there might be an increased risk of renal toxicity. As anaesthetic veterinary medicinal products 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 (bw) once daily as presented in the table below.

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 (bw) 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.

bw (kg)	Number of chewable tablets by size		mg/kg bw range
	25 mg	100 mg	
3.0 – 3.5	0.75		5.4 – 6.25
3.6 – 5	1	0.25	5.0 – 6.9
5.1 – 6	1.25		5.2 – 6.1
6.1 – 7.5	1.5		5.0 – 6.1
7.6 – 8.5	1.75		5.1 – 5.8
8.6 – 10	2	0.5	5.0 – 5.8
10.1 – 15		0.75	5.0 – 7.4
15.1 – 20		1	5.0 – 6.6
20.1 – 25		1.25	5.0 – 6.2
25.1 – 30		1.5	5.0 – 6.0
30.1 – 35		1.75	5.0 – 5.8
35.1 – 40		2	5.0 – 5.7

or

bw (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

or

bw (kg)	Number of chewable tablets by size		mg/kg bw range
	225 mg		
18.4 – 22.5	0.5		5.0 – 6.1
22.6 – 33.5	0.75		5.0 – 7.5
33.6 – 45	1		5.0 – 6.7
45.1 – 56	1.25		5.0 – 6.2
56.1 – 67	1.5		5.0 – 6.1
67.1 – 78	1.75		5.0 – 5.9
78.1 – 90	2		5.0 – 5.8

Tablets can be administered with or without food.

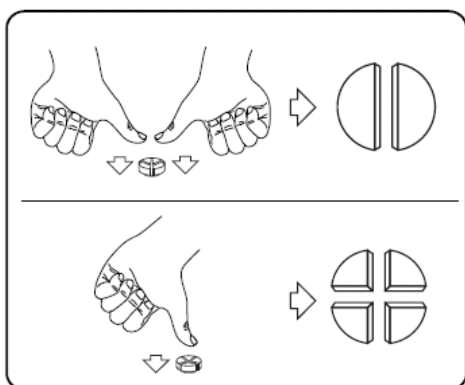
Tablets can be divided into 2 or 4 equal parts to enable accurate dosing.

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<sub>50</sub>) is 0.16 (± 0.05) µM, whereas the IC<sub>50</sub> 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<sub>max</sub>) is 1.25 (± 0.85) hours. The peak concentration (C<sub>max</sub>) is 0.52 (± 0.22) mcg/ml (equivalent to approximately 1.5 µM), area under the curve (AUC<sub>0-24</sub>) is 4.63 (± 1.91) mcg 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.

### **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.

#### **5.3 Special precautions for storage**

This veterinary medicinal product does not require any special storage conditions.

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

Aluminium - PVC/PE/PVDC blister in cardboard box, containing 10 chewable tablets each.

Package sizes:

Cardboard box with 10, 20, 30, 50, 100 or 200 chewable 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**

CP-Pharma Handelsgesellschaft mbH

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

EU/2/22/286/001-024

**8. DATE OF FIRST AUTHORISATION**

Date of first authorisation: 12/08/2022

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

{DD/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) (<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**

Coxatab 25 mg chewable tablets  
Coxatab 57 mg chewable tablets  
Coxatab 100 mg chewable tablets  
Coxatab 225 mg chewable tablets

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each chewable tablet contains:

Firocoxib	25 mg
Firocoxib	57 mg
Firocoxib	100 mg
Firocoxib	225 mg

**3. PACKAGE SIZE**

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

**4. TARGET SPECIES**

Dogs.



**5. INDICATIONS**

**6. ROUTES OF ADMINISTRATION**

Oral 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**

EU/2/22/286/001 (25 mg, 10 tablets)  
EU/2/22/286/002 (25 mg, 20 tablets)  
EU/2/22/286/003 (25 mg, 30 tablets)  
EU/2/22/286/004 (25 mg, 50 tablets)  
EU/2/22/286/005 (25 mg, 100 tablets)  
EU/2/22/286/006 (25 mg, 200 tablets)  
EU/2/22/286/007 (57 mg, 10 tablets)  
EU/2/22/286/008 (57 mg, 20 tablets)  
EU/2/22/286/009 (57 mg, 30 tablets)  
EU/2/22/286/010 (57 mg, 50 tablets)  
EU/2/22/286/011 (57 mg, 100 tablets)  
EU/2/22/286/012 (57 mg, 200 tablets)  
EU/2/22/286/013 (100 mg, 10 tablets)  
EU/2/22/286/014 (100 mg, 20 tablets)  
EU/2/22/286/015 (100 mg, 30 tablets)  
EU/2/22/286/016 (100 mg, 50 tablets)  
EU/2/22/286/017 (100 mg, 100 tablets)  
EU/2/22/286/018 (100 mg, 200 tablets)  
EU/2/22/286/019 (225 mg, 10 tablets)  
EU/2/22/286/020 (225 mg, 20 tablets)  
EU/2/22/286/021 (225 mg, 30 tablets)  
EU/2/22/286/022 (225 mg, 50 tablets)  
EU/2/22/286/023 (225 mg, 100 tablets)  
EU/2/22/286/024 (225 mg, 200 tablets)

**15. BATCH NUMBER**

Lot {number}



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

**Blister foil**

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

Coxatab  
Coxatab  
Coxatab  
Coxatab



**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

Firocoxib	25 mg/ chewable tablet
Firocoxib	57 mg/ chewable tablet
Firocoxib	100 mg/ chewable tablet
Firocoxib	225 mg/ chewable tablet

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

**B. PACKAGE LEAFLET**



## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

Coxatab 25 mg chewable tablets for dogs  
Coxatab 57 mg chewable tablets for dogs  
Coxatab 100 mg chewable tablets for dogs  
Coxatab 225 mg chewable tablets for dogs

### 2. Composition

Each chewable tablet contains:

#### Active substance:

##### Coxatab 25 mg chewable tablets

Firocoxib 25 mg

##### Coxatab 57 mg chewable tablets

Firocoxib 57 mg

##### Coxatab 100 mg chewable tablets

Firocoxib 100 mg

##### Coxatab 225 mg chewable tablets

Firocoxib 225 mg

Off-white to light brown, speckled with brown spots, round and convex chewable 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.
- in pregnant or lactating bitches.
- in animals less than 10 weeks of age or less than 3 kg body weight.
- in animals suffering from gastrointestinal bleeding, blood dyscrasia or haemorrhagic disorders.

## **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 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:

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 veterinary medicinal products may result in additional or increased adverse effects and accordingly a treatment-free period with such veterinary medicinal products should be observed for at least 24 hours before the commencement of treatment with the veterinary medicine. The treatment-free period, however, should take into account the pharmacokinetic properties of the veterinary medicinal 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 veterinary medicinal products should be avoided as there might be an increased risk for renal toxicity. As anaesthetic veterinary medicinal products 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

Dogs:

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

<sup>1</sup> 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

Oral use.

5 mg/kg bodyweight (bw) 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.

bw (kg)	Number of chewable tablets by size		mg/kg bw range
	25 mg	100 mg	
3.0 – 3.5	0.75		5.4 – 6.25
3.6 – 5	1	0.25	5.0 – 6.9
5.1 – 6	1.25		5.2 – 6.1
6.1 – 7.5	1.5		5.0 – 6.1
7.6 – 8.5	1.75		5.1 – 5.8
8.6 – 10	2	0.5	5.0 – 5.8
10.1 – 15		0.75	5.0 – 7.4
15.1 – 20		1	5.0 – 6.6
20.1 – 25		1.25	5.0 – 6.2
25.1 – 30		1.5	5.0 – 6.0
30.1 – 35		1.75	5.0 – 5.8
35.1 – 40		2	5.0 – 5.7

or

bw (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

or

bw (kg)	Number of chewable tablets by size		mg/kg bw range
	225 mg		
18.4 – 22.5	0.5		5.0 – 6.1
22.6 – 33.5	0.75		5.0 – 7.5
33.6 – 45	1		5.0 – 6.7
45.1 – 56	1.25		5.0 – 6.2
56.1 – 67	1.5		5.0 – 6.1
67.1 – 78	1.75		5.0 – 5.9
78.1 – 90	2		5.0 – 5.8

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

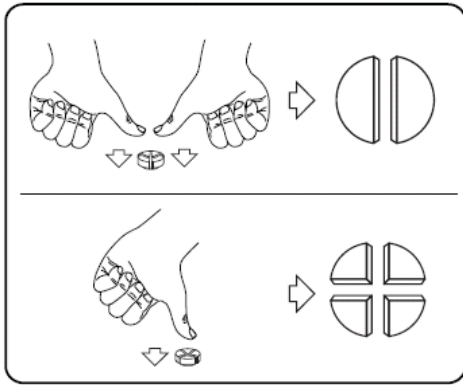
Place the tablet on a flat surface, with its scored side facing up and the convex (rounded) side facing the surface.

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 periods**

Not applicable.

#### **11. Special storage precautions**

Keep out of the sight and reach of children.

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 and the carton 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 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.

#### **14. Marketing authorisation numbers and pack sizes**

EU/2/22/286/001- 024

Aluminium - PVC/PE/PVDC blister, containing 10 chewable tablets each.

Package sizes:

Cardboard box with 10, 20, 30, 50, 100 or 200 chewable tablets.

Not all pack sizes may be marketed.

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

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

#### **16. Contact details**

Marketing authorisation holder and manufacturer responsible for batch release:

CP-Pharma Handelsgesellschaft mbH  
Ostlandring 13  
DE-31303 Burgdorf

Local representative and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

##### **België/Belgique/Belgien**

Alivira NV  
Kolonel Begaultlaan 1a  
BE-3012 Leuven  
Tél/Tel: +32 16 84 19 79  
PHV@alivira.be

##### **Lietuva**

OÜ Zoovetvaru  
Uusaru 5,  
76505 Saue,  
Estija  
Tel: + 372 6 709 006

##### **Република България**

CP- Pharma Handelsgesellschaft mbH  
Ostlandring 13  
31303 Burgdorf  
Германия  
Тел: +49 (0)5136 60660

##### **Luxembourg/Luxemburg**

Alivira NV  
Kolonel Begaultlaan 1a  
3012 Leuven  
Belgium/Belgien  
Tél/Tel: +32 16 84 19 79  
PHV@alivira.be

##### **Česká republika**

WERFFT, spol. s r.o.  
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**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.

The tablets of this veterinary medicinal product are scored to facilitate accurate dosing and contain hydrolysed chicken flavour to facilitate administration to dogs.