1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ficoxil 57 mg chewable tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains:

Active substance:
Firocoxib 57 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Lactose monohydrate	
Povidone	
Crospovidone	
Croscarmellose sodium	
Silica, colloidal anhydrous	
Magnesium stearate	
Beef flavour	
Red iron oxide (E172)	0.131 mg
Yellow iron oxide (E172)	0.056 mg

Biconvex rosaceous round tablets with a double groove on one side without inscriptions.
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).
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
As the tablets are flavoured, they should be stored in a safe place out of the reach of animals.
The recommended dose, as indicated in the dosing table, 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 any 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 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:
This veterinary medicinal product may be harmful following accidental ingestion.
In order to prevent children from accessing the veterinary medicinal product, tablets should be administered and stored out of sight and reach of children. Halved or quartered tablets should be returned to the open blister pocket and inserted into the outer carton.
Laboratory studies in rats and rabbits have shown evidence that firocoxib has the potential to effect reproduction and to induce malformations in foetuses. Pregnant women or women who are intending to become pregnant should administer the veterinary medicinal product with caution.
Wash hands after use of the veterinary medicinal product.
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.

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[1,2], diarrhoea[1,2]
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

Undetermined frequency (cannot be estimated from the available data):	Blood in faeces[2] Weight loss[2,3], anorexia[2], lethargy[2] Elevated renal parameters[2] Elevated liver enzymes[2]

[1] Generally of a transitory nature and reversible when the treatment is stopped.
[2] In case of occurrence, use of the veterinary medicinal product should be stopped and the advice of a veterinarian should be sought.
[3](sudden)

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

Laboratory studies in rabbits have shown evidence of maternotoxic and foetotoxic effects at dose rates approximating the recommended treatment dose for the dog.

Pregnancy and lactation:
Do not use in pregnant or lactating bitches.

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 firocoxib per kg bodyweight 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 firocoxib 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.

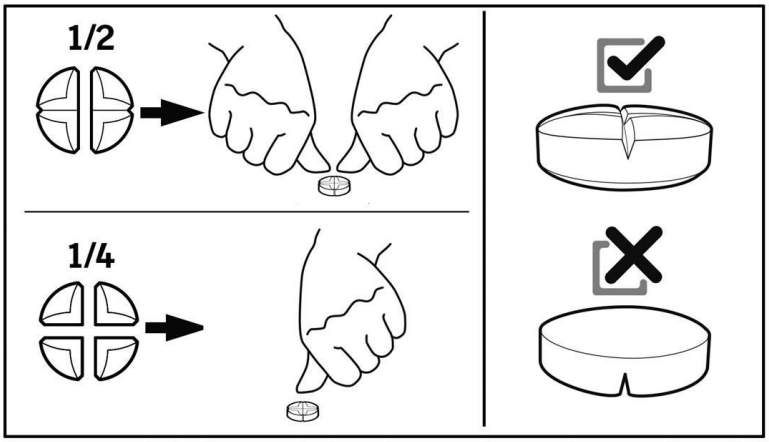
Following orthopaedic surgery and depending on the response observed, treatment using the same daily dosing schedule may be continued after the first 3 days, upon judgement of the attending veterinarian.

The following table is intended as a guideline for administering the veterinary medicinal product at the recommended dose.

Body weight (kg)	Number of tablets by size		mg/kg range
	57 mg	227 mg	
3.0 – 5.5	½		5.2 – 9.5
5.6- 7.5	¾		5.7 – 7.6
7.6-10	1 or ¼		5.7 – 7.5
10.1- 13	1 ¼		5.5 – 7.1
13.1 - 16	1 ½		5.3 – 6.5
16.1-18.5	1 ¾		5.4 – 6.2
18.6-22.5		½	5.0 – 6.1
22.6-34		¾	5.0 – 7.5
34.1-45		1	5.0 – 6.7
45.1-56		1 ¼	5.1 – 6.3
56.1-68		1 ½	5.0 – 6.1
68.1-79		1 ¾	5.0 – 5.8
79.1-90		2	5.0 – 5.7

 = ¼ Tablet  = ½ Tablet  = ¾ Tablet  = 1 Tablet

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



Tablets can be administered with or without food.

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 2.43 (± 1.04) hours. The peak concentration (C_{max}) is 1.11 (± 0.47) µg/ml, plasma concentrations-time can exhibit a bimodal distribution with a potential entero-hepatic cycle, area under the curve ($AUC_{t\text{-}last}$) is 8.88 (±3.66) µg x hr/ml, and oral bioavailability is 36.9 (± 20.4) percent. The terminal half-life ($t_{½}$) is 5.71 (± 1.51) hours (harmonic mean 5.33 h). 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.
Any remaining tablet portion should be returned to the blister and given at the next administration within 7 days.

5.4 Nature and composition of immediate packaging

Transparent PVDC-PE-PVC/aluminium blisters or PVC-aluminium-OPA/aluminium blisters.

Package 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 6 blisters of 10 tablets (60 tablets).
- 1 cardboard box containing 10 blisters of 10 tablets (100 tablets).
- 1 cardboard box containing 18 blisters of 10 tablets (180 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

Industrial Veterinaria, S.A.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10509/024/001

8. DATE OF FIRST AUTHORISATION

18/06/2021

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

24/04/2026

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).