Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Ficoxil 227 mg chewable tablets for dogs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:

Firocoxib	227	mg

Excipients:

Red iron oxide (E172)	0.525	mg
Yellow iron oxide(E172)	0.225	mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

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

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

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 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 product may be harmful following accidental ingestion.
In order to prevent children from accessing the 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 product with caution.
Wash hands after use of the 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.

4.6 Adverse reactions (frequency and seriousness)

Emesis and diarrhoea have occasionally been reported. These reactions are generally of a transitory nature and are reversible when the treatment is stopped. Renal and/or hepatic disorders have been reported in very rare cases in dogs administered the recommended treatment dose. Rarely, nervous system disorders have been reported in treated dogs.

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.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 interactions

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 product. The treatment-free period, however, should take into account the pharmacokinetic properties of the products 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 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 Amounts to be administered and administration route

For 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.

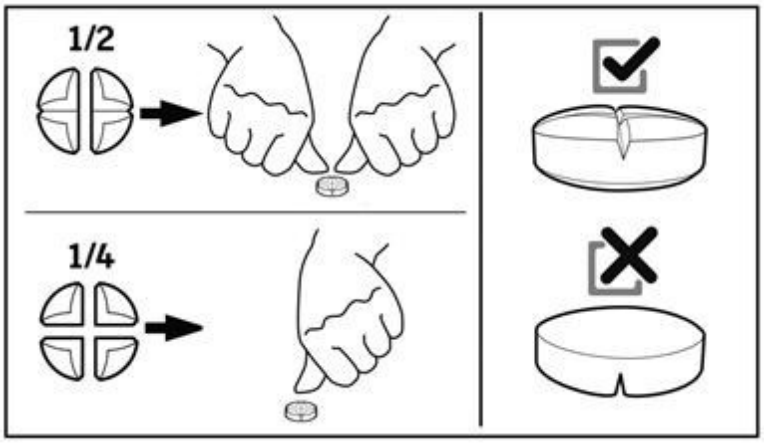
Relief of post-operative pain:
Administer 5 mg firocoxib per kg bodyweight once daily as presented in the table below for up to 3 days as needed, starting approximately 2 hours prior to surgery.

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

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



Tablets can be administered with or without food.

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 or IMMUNOLOGICAL 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 IC_{50}) is 0.16 (± 0.05) µM, whereas the IC_{50} 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 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Povidone
Crospovidone
Croscarmellose sodium
Silica, colloidal anhydrous
Magnesium stearate
Beef flavour
Red iron oxide (E172)

Yellow iron oxide (E172)

6.2 Major incompatibilities

Not applicable.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

6.4 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.

6.5 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

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

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

Industrial Veterinaria S.A.

8 MARKETING AUTHORISATION NUMBER(S)

VPA10509/024/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18 June 2021

10 DATE OF REVISION OF THE TEXT

15/01/2026