SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cimalgex 30 mg chewable tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains:

Active substance:
cimicoxib 30 mg

Excipients:

Qualitative composition of excipients and other constituents
Lactose monohydrate
Povidone K25
Crospovidone
Sodium laurylsulfate
Macrogol 400
Sodium stearyl fumarate
Pork liver powder

Oblong, white to pale brown, chewable tablets with 2 break-lines on both sides. The tablets can be divided into equal thirds.

3. CLINICAL INFORMATION

3.1 Target species

Dogs

3.2 Indications for use for each target species

For the treatment of pain and inflammation associated with osteoarthritis, and the management of peri- operative pain due to orthopaedic or soft tissue surgery, in dogs.

3.3 Contraindications

Do not use in dogs less than 10 weeks of age.
Do not use in dogs suffering from gastrointestinal disorders or haemorrhagic disorders.
Do not use concomitantly with corticosteroids or other non-steroidal anti-

inflammatory drugs (NSAIDs). Refer also to section 4.8
Do not use in case of hypersensitivity to cimicoxib or to any of the excipients.
Do not use in breeding, pregnant and lactating animals.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Since the safety of the medicinal product has not been adequately demonstrated in young animals, careful monitoring is advised during the treatment of young dogs aged less than 6 months.
Use in animals suffering from impaired cardiac, renal or hepatic function, may involve additional risk. If such use cannot be avoided, these animals require careful veterinary monitoring.

Avoid using this veterinary medicinal product in any animals which are dehydrated, hypovolaemic or hypotensive, as it may increase the risk of renal toxicity.

Use this veterinary medicinal product under strict veterinary monitoring where there is a risk of gastrointestinal ulceration, or if the animal previously displayed intolerance to NSAIDs.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

This veterinary medicinal product may cause skin sensitisation. Wash hands after use.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
People with a known hypersensitivity to cimicoxib should avoid contact with the veterinary medicinal product.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

Very common (>1 animal / 10 animals treated):	Vomiting[1], Diarrhoea[1]
Rare (1 to 10 animals / 10,000 animals treated):	Digestive tract haemorrhage[2], Gastric ulceration[2], Anorexia, Lethargy, Polyuria, Polydipsia
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Elevated renal parameters, Renal failure[3]

[1] *Mild and transient gastro-intestinal disorders*
[2] *Serious gastro-intestinal disorders*
[3]*Kidney function should be monitored during long-term NSAID treatment.*
If any observed adverse effect persists after stopping treatment, the advice of a veterinarian should be sought.

If adverse reactions such as persistent vomiting, repeated diarrhoea, faecal occult blood, sudden weight loss, anorexia, lethargy or worsening of renal or hepatic biochemistry parameters occur, use of the product should be discontinued and appropriate monitoring and/or treatment should be put in place. As with other NSAIDs, serious adverse effects can occur and, in 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 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

Do not use in breeding, pregnant or lactating bitches.

Although no data are available in dogs, studies with laboratory animals have shown effects on their fertility and foetal development.

3.8 Interaction with other medicinal products and other forms of interaction

Cimicoxib should not be administered in conjunction with corticosteroids or other NSAIDs. 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 before the commencement of treatment with cimicoxib. The treatment-free period should take into account the pharmacokinetic properties of the veterinary medicinal product used previously.

3.9 Administration routes and dosage

Oral use.

The recommended dose of cimicoxib is 2 mg/kg bodyweight, once daily.
The following table is presented as an example of how the tablets and tablet parts could be used in order to reach the recommended dose.

Bodyweight kg	8 mg	30 mg	80 mg
2	1/2		
3	1		
4	1		
5		1/3	
6	1+1/2		
7-8	2		
9-11	2+1/2		
12	3		
13-17		1	
18-22			1/2
23-28		1+2/3	
29-33		2	
34-38		2+1/3	
39-44			1
45-48		3	
49-54			1+1/4
55-68			1+1/2

The choice of the most suitable tablet type or tablet parts is left to the discretion of the veterinarian based on the circumstances in each case, without leading to important over- or underdosing.

Treatment duration:

- Management of peri-operative pain due to orthopaedic or soft tissue surgeries: one dose 2 hours prior to surgery, followed by 3 to 7 days of treatment, based on the judgment of the attending veterinarian.
- Relief of pain and inflammation associated with osteoarthritis: 6 months. For longer-term
  treatment, regular monitoring should be undertaken by the veterinarian.

The veterinary medicinal product can be administered with or without food. The tablets are flavoured and studies (in healthy Beagle dogs) show they are likely to be taken voluntarily by most dogs.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

In an overdose study where 3 times (5.8 to 11.8 mg/kg body weight) and 5 times (9.7 to 19.5 mg/kg body weight) the recommended dose was administered to dogs for a period of 6 months, a dose related increase in gastrointestinal disturbances, which affected all dogs in the highest dose group, was noted.

Similar dose related changes to haematology and white blood cell counts, as well as renal integrity, were also noted.

As with any NSAID, overdose may cause gastrointestinal, kidney, or liver toxicity in sensitive or compromised dogs.

There is no specific antidote to this product. Symptomatic, supportive therapy is recommended consisting of administration of gastrointestinal protective agents and infusion of isotonic saline.

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 period

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QM01AH93

4.2 Pharmacodynamics

Cimicoxib is a non-steroidal anti-inflammatory drug belonging to the coxib group and acting by selective inhibition of the enzyme cyclo-oxygenase 2. The cyclo-oxygenase enzyme (COX) is present in two isoforms. COX-1 is usually a constitutive enzyme expressed in tissues, which synthesize products responsible for normal physiologic functions (e.g. in the gastro-intestinal tract and kidneys). COX-2 on the other hand, is mainly inducible and synthesized by macrophages and inflammatory cells after stimulation by cytokines and other mediators of inflammation. COX-2 is involved in the production of mediators, including PGE2, that induce pain, exudation, inflammation and fever.

In an *in vivo* inflammatory acute pain model, it was shown that the simulated effect of cimicoxib lasted for approximately 10-14 hours.

4.3 Pharmacokinetics

After oral administration in dogs at the recommended dose of 2 mg/kg without food, cimicoxib is rapidly absorbed and the time to maximal concentration (T_{max}) is 2.25 (± 1.24) hours. The peak concentration (C_{max}) is 0.3918 (± 0.09021) µg/ml, area under the curve (AUC) is 1.676 (± 0.4735) µg.hr/ml, and oral bioavailability is 44.53 (± 10.26) percent.

The oral administration of cimicoxib with food did not significantly influence the bioavailability but decreased significantly the observed T_{max}.

Metabolism of cimicoxib is extensive. The major metabolite, demethylated cimicoxib is mainly eliminated in faeces by the biliary route and, to a lesser extent, in urine. The other metabolite, glucuronide conjugate of the demethylated cimicoxib, is eliminated in urine. The elimination half-life ($t_{1/2}$) is 1.38 (± 0.24)

hours. The metabolising enzymes have not been fully investigated and slower metabolism (up to four-fold increased exposure) has been noted in some individuals.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

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

Any remaining divided tablets should be discarded after 2 days storage in the blisters.
Any remaining divided tablets should be discarded after 90 days storage in the bottle.

5.3 Special precautions for storage

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

Any divided tablets should be stored in the blister pack/bottle.

5.4 Nature and composition of immediate packaging

All strengths are available in the following pack sizes and types:

- Aluminium blisters (each strip containing 8 chewable tablets) packaged into an outer cardboard box. Pack sizes of 8, 32 or 144 chewable tablets.
- Plastic (HDPE) bottle with child resistant plastic (PP) closure packaged into an outer cardboard box. Pack sizes of 45 chewable tablets.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater.

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. MARKETING AUTHORISATION HOLDER

Vetoquinol SA

7. MARKETING AUTHORISATION NUMBER

Vm 06462/5000

8. DATE OF FIRST AUTHORISATION

18 February 2011

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

February 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Gavin Hall
Approved: 19 September 2025