SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cimalgex 8 mg chewable tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:
Cimalgex 8 mg cimicoxib 8 mg

For the full list of excipients see section 6.1.

3. PHARMACEUTICAL FORM

Chewable tablets.
Cimalgex 8 mg, tablets: oblong, white to pale brown, chewable tablets with 1 break-line on both sides.The tablets can be divided into equal halves.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the 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.

4.3 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.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

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 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

Cimicoxib 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.

4.6 Adverse reactions (frequency and seriousness)

Mild and transient gastro-intestinal disorders (vomiting and/or diarrhoea) were very commonly reported.

On rare occasions, serious gastrointestinal disorders such as haemorrhage and ulcer formation have been noted. Other adverse reactions including anorexia or lethargy or polyuria and/or polydipsia may also be observed on rare occasions.

In very rare cases, increases in renal biochemistry parameters were noted. Furthermore, in very rare cases, renal failure has been reported. As for any long term NSAID treatment, renal function should be monitored.

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. Severe gastrointestinal and renal adverse events may be fatal.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)

- very rare (less than 1 animal in 10,000 animals, including isolated reports).

4.7 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.

4.8 Interaction with other medicinal products and other forms of interaction

Cimalgex 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 Cimalgex. The treatment-free period should take into account the pharmacokinetic properties of the veterinary medicinal product used previously.

4.9 Amounts to be administered and administration route

Oral use.

The recommended dose of cimicoxib is 2 mg per 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	
39-43			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.

Cimalgex tablets 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: non-steroidal anti-inflammatory drug, ATCvet code: QM01AH93

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Povidone K25
Crospovidone
Sodium laurylsulfate
Macrogol 400
Sodium stearyl fumarate
Pork liver powder

6.2 Incompatibilities

None known.

6.3 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.

6.4. 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.

6.5 Nature and composition of immediate packaging

All strengths are available in the following pack sizes and types:
- Aluminium blisters (each strip containing 8 tablets) packaged into an outer cardboard box. Pack sizes of 8, 32 or 144 tablets.
- Plastic (HDPE) bottle with child resistant plastic (PP) closure packaged into an outer cardboard box. Pack sizes of 45 tablets.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Vetoquinol SA
Magny-Vernois
70200 Lure
France

8. MARKETING AUTHORISATION NUMBER

06462/5002

9. DATE OF FIRST AUTHORISATION

18/02/2011

10. DATE OF REVISION OF THE TEXT

January 2024

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency: http://www.ema.europa.eu/

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable

Approved 28 April 2024