

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Outer carton (for both blisters and bottle)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cimalgex 8 mg chewable tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each chewable tablet contains 8 mg cimicoxib

3. PACKAGE SIZE

8 chewable tablets
32 chewable tablets
144 chewable tablets
45 chewable tablets

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

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.

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

Vetoquinol SA

14. MARKETING AUTHORISATION NUMBERS

Vm 06462/5002

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle pack

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cimalgex



2. QUANTATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Cimicoxib 8 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp {mm/yyyy}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cimalgex



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Cimicoxib 8 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp {mm/yyyy}

Vetoquinol Logo

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Cimalgex 8 mg chewable tablets for dogs

Cimalgex 30 mg chewable tablets for dogs

Cimalgex 80 mg chewable tablets for dogs

2. Composition

Each chewable tablet contains:

Active substance:

<u>Cimalgex 8 mg</u>	
Cimicoxib	8 mg

<u>Cimalgex 30 mg</u>	
Cimicoxib	30 mg

<u>Cimalgex 80 mg</u>	
Cimicoxib	80 mg

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

Cimalgex 30 mg chewable tablets: oblong, white to pale brown, chewable tablets with 2 break-lines on both sides. The tablets can be divided into equal thirds.

Cimalgex 80 mg chewable tablets: oblong, white to pale brown, chewable tablets with 3 break-lines on both sides. The tablets can be divided into equal quarters.

3. Target species

Dogs.

4. Indications for use

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.

5. Contraindications

Do not use in dogs less than 10 weeks of age.

Do not use in dogs suffering from stomach or digestive system disorders or in dogs with bleeding problems.

Do not use at the same time as corticosteroids or other non-steroidal anti-inflammatory drugs (NSAIDs).

Do not use if the dog is hypersensitive to the active substance or any of the excipients.

Do not use in breeding, pregnant or lactating animals (see Section 6 “Pregnancy and lactation”).

6. Special warnings

Special precautions for safe use in the target species:

The safety of this medicinal product has not been adequately demonstrated in young dogs, so careful monitoring by your veterinary surgeon is recommended if the dog is less than 6 months of age.

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 in dogs with a risk of stomach ulcers or if the animal previously displayed intolerance to other 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 of the veterinary medicinal product.

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.

Pregnancy and lactation:

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.

Interactions 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 starting treatment with Cimicoxib. The treatment-free period should take into account the pharmacokinetic properties of the veterinary medicinal products used previously.

Overdose:

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 veterinary medicinal product. Symptomatic, supportive therapy is recommended consisting of administration of gastrointestinal protective agents and infusion of isotonic saline.

7. 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 disorder ² (e.g haemorrhage, ulceration, Anorexia (loss of appetite), Lethargy, Polydipsia (excessive thirst), Polyuria (frequent urination))
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Elevated renal parameters, Renal failure ³

1 Mild and transient

2 Serious

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 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 using the contact details at the end of this leaflet, or via your national reporting system at <https://www.gov.uk/report-veterinary-medicine-problem>.

8. Dosage for each species, routes and method of administration

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 your veterinary surgeon.
- Relief of pain and inflammation associated with osteoarthritis: 6 months. For longer-term treatment, regular monitoring should be undertaken by your veterinary surgeon.

The veterinary medicinal product can be given to dogs 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.

9. Advice on correct administration

None.

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.

Blister packs - Any remaining divided tablets should be stored in the blisters but discarded if not used within 2 days.

Bottles - Any remaining divided tablets should be stored in the bottle but discarded if not used within 90 days.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton or on the label 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.

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 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

Vm 06462/5002

Vm 06462/5000

Vm 06462/5001

All strengths of Cimalgex tablets 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 size of 45 chewable tablets.

Not all pack sizes may be marketed.

15. PID link (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. Contact details

Marketing authorization holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

Vetoquinol SA
34 Rue de Chene Sainte-Anne
Magny Vernois
70200 Lure
France
Tel: +44 1280 814 500

17. Other information

POM-V

Cimicoxib is a non-narcotic, non-steroidal anti-inflammatory drug (NSAID) drug. It selectively inhibits the cyclooxygenase 2 enzyme (COX-2), which is responsible for pain, inflammation or fever. The cyclooxygenase 1 enzyme (COX-1) which has protective functions, for example, in the digestive tract and kidneys, is not inhibited by cimicoxib.

After oral administration in dogs at the recommended doses, cimicoxib is rapidly absorbed. 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.

In an artificially induced pain model in dogs it was shown that the pain and inflammation reducing effects of cimicoxib lasted for approximately 10-14 hours.

Gavin Hall

Approved: 19 September 2025