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 for dogs

cimicoxib

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

8 mg cimicoxib

3. PHARMACEUTICAL FORM

Chewable tablets

4. PACKAGE SIZE

8 tablets
32 tablets
144 tablets
45 tablets

5. TARGET SPECIES

Dogs

6. INDICATIONS

7. METHOD AND ROUTES OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNINGS, IF NECESSARY

10. EXPIRY DATE

EXP {MM/YYYY}

11. SPECIAL STORAGE CONDITIONS

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read Package Leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE,

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol SA
Magny-Vernois
70200 Lure
France

16. MARKETING AUTHORISATION NUMBER(S)

06462/5002

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle pack

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cimalgex 8 mg tablets for dogs

cimicoxib

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

8 mg cimicoxib

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

45 tablets

4. ROUTES OF ADMINISTRATION

Oral use

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cimalgex 8 mg chewable tablets for dogs

cimicoxib

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Cimalgex 8 mg chewable tablets for dogs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Vetoquinol SA
Magny-Vernois
70200 Lure
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cimalgex 8 mg chewable tablets for dogs

Cimicoxib

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each tablet contains:
Cimicoxib 8 mg

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

4. INDICATIONS

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 cimicoxib or any of the other ingredients in the product.
Do not use in breeding, pregnant or lactating animals (see Section 12 “Special precautions for dogs”).

6. ADVERSE REACTIONS

Mild gastro-intestinal disorders (vomiting and/or diarrhoea) were very commonly reported but these only lasted for a short time.

On rare occasions, serious gastrointestinal problems such as bleeding and ulcer formation have occurred. Other adverse reactions including loss of appetite or lethargy or frequent urination and/or excessive thirst may also be observed on rare occasions.

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

If any observed adverse effect persists after stopping treatment, the advice of your veterinary surgeon should be sought.

If adverse reactions such as persistent vomiting, repeated diarrhoea, blood in the stools, sudden weight loss, loss of appetite, lethargy or worsening of liver or kidney function results occur, use of the product should be discontinued and the advice of your veterinary surgeon should be sought immediately. Severe adverse events in the gastrointestinal tract and kidneys may be fatal.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

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).

7. TARGET SPECIES

Dogs.

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

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 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.

Cimalgex tablets 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 PERIOD

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 label.

12. SPECIAL WARNINGS

Special precautions for use in animals

The safety of this veterinary medicinal product has not been established 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 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 for people

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.

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

Overdose (symptoms, emergency procedures, 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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required.
These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

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

15. OTHER INFORMATION

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.

All strengths of Cimalgex tablets 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 size of 45 tablets.

Not all pack sizes may be marketed.

Approved 28 April 2024