ANNEX 1

SUMMARY OF PRODUCT CHARACTERISTICS

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. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains:

Active substance:

Cimalgex 8 mg
Cimicoxib 8 mg

Cimalgex 30 mg
Cimicoxib 30 mg

Cimalgex 80 mg
Cimicoxib 80 mg

Excipients:

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

Cimalgex 8 mg chewable tablets: oblong, white to pale brown, chewable tablets with 1 break-line on both sides. The tablets 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. 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 3.8
Do not use in cases of hypersensitivity to the active substance 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 veterinary 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 disorder[2] (e.g. haemorrhage, ulceration), Anorexia, Lethargy, Polydipsia, Polyuria
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 veterinary medicinal 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 its local representative 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	
39-43			1
44-48		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 chewable 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 veterinary medicinal 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 periods

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) mcg/ml, area under the curve (AUC) is 1.676 (±0.4735) mcg.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 temperature 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 products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

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. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol SA

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/10/119/001-012

8. DATE OF FIRST AUTHORISATION

18/02/2011

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

{DD/MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX (for both blisters and bottle)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cimalgex 8 mg chewable tablets
Cimalgex 30 mg chewable tablets
Cimalgex 80 mg chewable tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each chewable tablet contains:

Cimicoxib 8 mg
Cimicoxib 30 mg
Cimicoxib 80 mg

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

EU/2/10/119/001 8 chewable tablets 8 mg (blister)
EU/2/10/119/002 32 chewable tablets 8 mg (blister)
EU/2/10/119/003 144 chewable tablets 8 mg (blister)
EU/2/10/119/004 45 chewable tablets 8 mg (bottle)
EU/2/10/119/005 8 chewable tablets 30 mg (blister)
EU/2/10/119/006 32 chewable tablets 30 mg (blister)
EU/2/10/119/007 144 chewable tablets 30 mg (blister)
EU/2/10/119/008 45 chewable tablets 30 mg (bottle)
EU/2/10/119/009 8 chewable tablets 80 mg (blister)
EU/2/10/119/010 32 chewable tablets 80 mg (blister)
EU/2/10/119/011 144 chewable tablets 80 mg (blister)
EU/2/10/119/012 45 chewable tablets 80 mg (bottle)

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BOTTLE LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cimalgex

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Cimicoxib 8 mg
Cimicoxib 30 mg
Cimicoxib 80 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cimalgex

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Cimicoxib 8 mg
Cimicoxib 30 mg
Cimicoxib 80 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:

Cimalgex 8 mg	
Cimicoxib	8 mg
Cimalgex 30 mg	
Cimicoxib	30 mg
Cimalgex 80 mg	
Cimicoxib	80 mg

Cimalgex 8 mg chewable tablets: oblong, white to pale brown, chewable tablets with 1 break-line on both sides. The tablets 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 in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in breeding, pregnant or lactating animals (see section “Special warnings”)

6. Special warnings

Special precautions for safe use in the target species:
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 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 veterinary medicinal 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 or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

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	
39-43			1

44-48		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 chewable 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 temperature 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 and on the blister or bottle 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 or household waste.

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

EU/2/10/119/001-012

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. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).

16. Other information

Marketing authorisation holder and manufacturer responsible for batch release:
Vetoquinol S.A.
Magny-Vernois
70200 LURE
France

Local representatives and contact details to report suspected adverse reactions:

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Sverige
Tel: +46 42 676 03

United Kingdom (Northern Ireland)
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Ireland
Tel: +44 1280 814 500

17. 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.