ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Previcox 57 mg chewable tablets for dogs
Previcox 227 mg chewable tablets for dogs
firocoxib

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains:

Active substance:

firocoxib	57 mg
or	
firocoxib	227 mg

Excipients:
Iron oxides (E172)
Caramel (E150d)

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Chewable tablets.
Tan-brown, round, convex, tablets with a cross-shaped break line on one side. The tablets can be divided into 2 or 4 equal parts.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

For the relief of pain and inflammation associated with osteoarthritis in dogs.
For the relief of post-operative pain and inflammation associated with soft-tissue, orthopaedic and dental surgery in dogs.

4.3 Contraindications

Do not use in pregnant or lactating bitches.
Do not use in animals less than 10 weeks of age or less than 3 kg body weight.
Do not use in animals suffering from gastrointestinal bleeding, blood dyscrasia or haemorrhagic disorders.
Do not use concomitantly with corticosteroids or other non-steroidal anti-inflammatory drugs (NSAIDs).

4.4 Special warnings

None.

4.5 Special precautions for use

Special precautions for use in animals

The recommended dose, see section 4.9, should not be exceeded.
Use in very young animals, or animals with suspected or confirmed impairment of renal, cardiac or hepatic function may involve additional risk. If such use cannot be avoided, those dogs require careful veterinary monitoring.

Avoid use in dehydrated, hypovolaemic or hypotensive animals, as there is a potential risk of increased renal toxicity. Concurrent administration of potentially nephrotoxic drugs should be avoided.
Use this product under strict veterinary monitoring where there is a risk of gastrointestinal bleeding, or if the animal previously displayed intolerance to NSAIDs. Renal and/or hepatic disorders have been reported in very rare cases in dogs administered the recommended treatment dose. It is possible that a proportion of such cases had sub-clinical renal or hepatic disease prior to the commencement of therapy. Therefore, appropriate laboratory testing to establish baseline renal or hepatic biochemistry parameters is recommended prior to and periodically during administration.

The treatment should be discontinued if any of these signs are observed: repeated diarrhoea, vomiting, faecal occult blood, sudden weight loss, anorexia, lethargy, degradation of renal or hepatic biochemistry parameters.

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

Wash hands after use of the product.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Divided tablets should be returned to the original package.

4.6 Adverse reactions (frequency and seriousness)

Emesis and diarrhoea have occasionally been reported. These reactions are generally of a transitory nature and are reversible when the treatment is stopped. Renal and/or hepatic disorders have been reported in very rare cases in dogs administered the recommended treatment dose. Rarely, nervous system disorders have been reported in treated dogs.

If adverse reactions like vomiting, repeated diarrhoea, faecal occult blood, sudden weight loss, anorexia, lethargy, degradation of renal or hepatic biochemistry parameters occur, use of the product should be stopped and the advice of a veterinarian should be sought. As with other NSAIDs, serious adverse effects can occur and, in very rare cases, may be fatal.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated- displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Do not use in pregnant or lactating bitches.
Laboratory studies in rabbits have shown evidence of maternotoxic and foetotoxic effects at dose rates approximating the recommended treatment dose for the dog.

4.8 Interaction with other medicinal products and other forms of interaction

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 for at least 24 hours before the commencement of treatment with Previcox. The treatment-free period, however, should take into account the pharmacokinetic properties of the products used previously.

Previcox must not be administered in conjunction with other NSAIDs or glucocorticosteroids. Gastrointestinal tract ulceration may be exacerbated by corticosteroids in animals given non-steroidal anti-inflammatory drugs.

Concomitant treatment with molecules displaying action on renal flow, e.g. diuretics or Angiotensin Converting Enzyme (ACE) inhibitors, should be subject to clinical monitoring. Concurrent administration of potentially nephrotoxic drugs should be avoided as there might be an increased risk of renal toxicity. As anaesthetic drugs may affect renal perfusion, the use of parenteral fluid therapy during surgery should be considered to decrease potential renal complications when using NSAIDs peri-operatively.

Concurrent use of other active substances that have a high degree of protein binding may compete with firocoxib for binding and thus lead to toxic effects.

4.9 Amounts to be administered and administration route

Oral use.

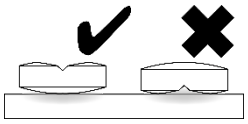
Osteoarthritis:
Administer 5 mg per kg bodyweight once daily as presented in the table below.
Tablets can be administered with or without food.
Duration of treatment will be dependent on the response observed. As field studies were limited to 90 days, longer-term treatment should be considered carefully and regular monitoring undertaken by the veterinarian.

Relief of post-operative pain:
Administer 5 mg per kg bodyweight once daily as presented in the table below for up to 3 days as needed, starting approximately 2 hours prior to surgery.

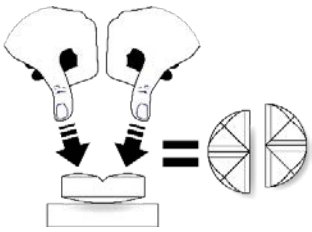
Following orthopaedic surgery and depending on the response observed, treatment using the same daily dosing schedule may be continued after the first 3 days, upon judgement of the attending veterinarian.

Body weight (kg)	**Number of chewable tablets by size**		**mg/kg range**
	57 mg	**227 mg**	
3.0 – 5.5	0.5		5.2 – 9.5
5.6 – 7.5	0.75		5.7 – 7.6
7.6 – 10	1	0.25	5.7 – 7.5
10.1 – 13	1.25		5.5 – 7.1
13.1 – 16	1.5		5.3 – 6.5
16.1 – 18.5	1.75		5.4 – 6.2
18.6 – 22.5		0.5	5.0 – 6.1
22.6 – 34		0.75	5.0 – 7.5
34.1 – 45		1	5.0 – 6.7
45.1 – 56		1.25	5.1 – 6.3
56.1 – 68		1.5	5.0 – 6.1
68.1 – 79		1.75	5.0 – 5.8
79.1 – 90		2	5.0 – 5.7

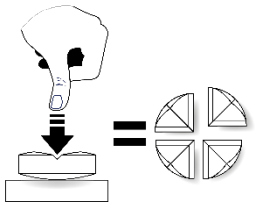
Tablets can be divided into 2 or 4 equal parts to enable accurate dosing.



Place the tablet on a flat surface, with its scored side facing up and the convex (rounded) side facing the surface.



To split into 2 equal parts: Press your thumbs down on both sides of the tablet.



To split into 4 equal parts: Press your thumb down in the middle of the tablet.

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

In dogs ten weeks of age, at the start of treatment, at dose rates equal or greater to 25 mg/kg/day (5 times the recommended dose) for three months, the following signs of toxicity were observed: bodyweight loss, poor appetite, changes in the liver (accumulation of lipid), brain (vacuolisation), duodenum (ulcers) and death. At dose rates equal or greater to 15 mg/kg/day (3 times the recommended dose) for six months, similar clinical signs were observed, albeit that the severity and frequency were less and duodenal ulcers were absent.
In those target animal safety studies, clinical signs of toxicity were reversible in some dogs following cessation of therapy.

In dogs seven months of age, at the start of treatment, at dose rates greater than or equal to 25 mg/kg/day (5 times the recommended dose) for six months, gastrointestinal adverse effects, i.e. vomiting were observed.

Overdose studies were not conducted in animals over 14 months of age.

If clinical signs of overdosing are observed, discontinue treatment.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anti-inflammatory and anti-rheumatic products, non-steroids.
ATCvet code: QM01AH90.

5.1 Pharmacodynamic properties

Firocoxib is a non-steroidal anti-inflammatory drug (NSAID) belonging to the Coxib group, which acts by selective inhibition of cyclooxygenase-2 (COX-2) – mediated prostaglandin synthesis. Cyclooxygenase is responsible for generation of prostaglandins. COX-2 is the isoform of the enzyme that has been shown to be induced by pro-inflammatory stimuli and has been postulated to be primarily responsible for the synthesis of prostanoid mediators of pain, inflammation, and fever. Coxibs therefore display analgesic, anti-inflammatory and antipyretic properties. COX-2 is also thought to be involved in ovulation, implantation and closure of the *ductus arteriosus*, and central nervous system functions (fever induction, pain perception and cognitive function). In *in-vitro* canine whole blood assays, firocoxib exhibits approximately 380-fold selectivity for COX-2 over COX-1.

The concentration of firocoxib required to inhibit 50 % of the COX-2 enzyme (i.e., the IC_{50}) is 0.16 (± 0.05) µM, whereas the IC_{50} for COX-1 is 56 (± 7) µM.

5.2 Pharmacokinetic particulars

Following oral administration in dogs at the recommended dose of 5 mg per kg of bodyweight, firocoxib is rapidly absorbed and the time to maximal concentration (T_{max}) is 1.25 (± 0.85) hours. The peak concentration (C_{max}) is 0.52 (± 0.22) µg/ml (equivalent to approximately 1.5 µM), area under the curve (AUC 0-24) is 4.63 (±1.91) µg x hr/ml, and oral bioavailability is 36.9 (± 20.4) percent. The elimination half-life ($t_{½}$) is 7.59 (± 1.53) hours. Firocoxib is approximately 96 % bound to plasma proteins. Following multiple oral administrations, the steady state is reached by the third daily dose. Firocoxib is metabolised predominantly by dealkylation and glucuronidation in the liver. Elimination is principally in the bile and gastrointestinal tract.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose Monohydrate
Microcrystalline Cellulose
Chartor Hickory Smoke Flavour
Hydroxypropyl cellulose
Croscarmellose Sodium
Magnesium Stearate
Caramel (E150d)
Silica, colloidal anhydrous
Yellow iron oxide (E172)
Red iron oxide (E172)

6.2 Major incompatibilities

Not applicable.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 4 years.

Divided tablets may be stored for up to 1 month in the original package.

6.4 Special precautions for storage

Do not store above 30°C.
Store in the original package.

6.5 Nature and composition of immediate packaging

Previcox tablets are supplied in blisters (transparent PVC /aluminium foil) or in 30 ml or 100 ml high density polyethylene bottles (with polypropylene closure).

The chewable tablets (57 mg or 227 mg) are available in the following pack sizes:

- 1 cardboard box containing 1 blister of 10 tablets (10 tablets).
- 1 cardboard box containing 3 blisters of 10 tablets (30 tablets).
- 1 cardboard box containing 18 blisters of 10 tablets (180 tablets) .
- 1 cardboard box containing 1 bottle of 60 tablets.

Not all pack sizes may be marketed.

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 products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/04/045/001-006
EU/2/04/045/008-009

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13/09/2004
Date of last renewal: 29/05/2009

10. DATE OF REVISION OF THE TEXT

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.

ANNEX II

A. MANUFACTURER(S) RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Boehringer Ingelheim Animal Health France SCS
4 Chemin de Calquet
31000 Toulouse
France

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

Not applicable.

D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

Not applicable.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box labelling

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Previcox 57 mg chewable tablets for dogs
Previcox 227 mg chewable tablets for dogs
firocoxib

2. STATEMENT OF ACTIVE SUBSTANCES

firocoxib 57 mg
firocoxib 227 mg

3. PHARMACEUTICAL FORM

Chewable tablet

4. PACKAGE SIZE

10 chewable tablets
30 chewable tablets
60 chewable tablets
180 chewable tablets

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

Pain and inflammation associated with osteoarthritis.
Peri-operative pain management.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Divided tablets may be stored for up to 1 month in the original package.

11. SPECIAL STORAGE CONDITIONS

Do not store above 30 °C.

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, if applicable

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

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/04/045/001 10 tablets
EU/2/04/045/002 30 tablets
EU/2/04/045/003 10 tablets
EU/2/04/045/004 30 tablets
EU/2/04/045/005 180 tablets
EU/2/04/045/006 180 tablets
EU/2/04/045/008 60 tablets
EU/2/04/045/009 60 tablets

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle of 100 ml labelling

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Previcox 227 mg chewable tablets for dogs
firocoxib

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Firocoxib 227 mg

3. PHARMACEUTICAL FORM

Chewable tablet

4. PACKAGE SIZE

60 chewable tablets

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Divided tablets may be stored for up to 1 month in the original package.

11. SPECIAL STORAGE CONDITIONS

Do not store above 30 °C.

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

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

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

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

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/04/045/009 60 tablets

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister foil

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Previcox 57 mg chewable tablets
Previcox 227 mg chewable tablets

firocoxib

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle label (30 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Previcox 57 mg chewable tablets for dogs
firocoxib

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Firocoxib 57 mg

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

60 chewable tablets

4. ROUTE(S) 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.

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Previcox 57 mg chewable tablets for dogs
Previcox 227 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

Marketing authorisation holder:
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

Manufacturer responsible for batch release:
Boehringer Ingelheim Animal Health France SCS,
4 Chemin du Calquet, 31000 Toulouse, France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Previcox 57 mg chewable tablets for dogs
Previcox 227 mg chewable tablets for dogs
firocoxib

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each chewable tablet contains:

Active substance:
firocoxib 57 mg
or
firocoxib 227 mg

Excipients:
Iron oxides (E172)
Caramel (E150d)

Tan-brown, round, convex, tablets with a cross-shaped break line on one side. The tablets can be divided into 2 or 4 equal parts.

4. INDICATION(S)

For the relief of pain and inflammation associated with osteoarthritis in dogs.
For the relief of post-operative pain and inflammation associated with soft-tissue, orthopaedic and dental surgery in dogs.

5. CONTRAINDICATIONS

Do not use in pregnant or lactating bitches.
Do not use in animals less than 10 weeks of age or less than 3 kg bodyweight.
Do not use in animals suffering from gastrointestinal bleeding, blood dyscrasia or haemorrhagic disorders.

Do not use concomitantly with corticosteroids or other non-steroidal anti-inflammatory drugs (NSAIDs).

6. ADVERSE REACTIONS

Emesis and diarrhoea have occasionally been reported. These reactions are generally of a transitory nature and are reversible when the treatment is stopped. Renal and/or hepatic disorders have been reported in very rare cases in dogs administered the recommended treatment dose. Rarely, nervous system disorders have been reported in treated dogs.

If adverse reactions like vomiting, repeated diarrhoea, faecal occult blood, sudden weight loss, anorexia, lethargy, degradation of renal or hepatic biochemistry parameters occur, use of the product should be stopped and the advice of a veterinarian should be sought. As with other NSAIDs, serious adverse effects can occur and, in very rare cases, may be fatal.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

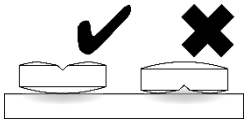
8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

5 mg/kg once daily.
For the reduction of post-operative pain and inflammation, the animals can be dosed starting approximately 2 hours before surgery for up to 3 consecutive days as needed. Following orthopaedic surgery and depending on the response observed, treatment using the same daily dosing schedule may be continued after the first 3 days, upon judgement of the attending veterinarian.

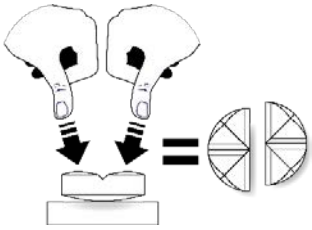
For oral use as per table below.

Body weight (kg)	**Number of chewable tablets by size**		**mg/kg range**
	57 mg	**227 mg**	
3.0 – 5.5	0.5		5.2 – 9.5
5.6 – 7.5	0.75		5.7 – 7.6
7.6 – 10	1	0.25	5.7 – 7.5
10.1 – 13	1.25		5.5 – 7.1
13.1 – 16	1.5		5.3 – 6.5
16.1 – 18.5	1.75		5.4 – 6.2
18.6 – 22.5		0.5	5.0 – 6.1
22.6 – 34		0.75	5.0 – 7.5
34.1 – 45		1	5.0 – 6.7
45.1 – 56		1.25	5.1 – 6.3
56.1 – 68		1.5	5.0 – 6.1
68.1 – 79		1.75	5.0 – 5.8
79.1 – 90		2	5.0 – 5.7

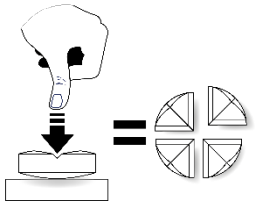
Tablets can be divided into 2 or 4 equal parts to enable accurate dosing.



Place the tablet on a flat surface, with its scored side facing up and the convex (rounded) side facing the surface.



To split in 2 equal parts:
Press your thumbs down on both sides of the tablet.



To split into 4 equal parts:
Press your thumb down in the middle of the tablet.

9. ADVICE ON CORRECT ADMINISTRATION

Tablets can be administered with or without food. Do not exceed the recommended dose.
Duration of treatment will be dependent on the response observed. As field studies were limited to 90 days, longer-term treatment should be considered carefully and regular monitoring undertaken by the veterinarian.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 30 °C.
Store in the original package.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP.
Divided tablets may be stored for up to 1 month in the original package.

12. SPECIAL WARNING(S)

Special precautions for use in animals:
Use in very young animals, or animals with suspected or confirmed impairment of renal, cardiac or hepatic function may involve additional risk. If such use cannot be avoided, those dogs require careful veterinary monitoring. Appropriate laboratory testing is recommended prior to treatment in order to detect subclinical (asymptomatic) renal or hepatic disorders that may predispose to adverse effects. Avoid use in dehydrated, hypovolaemic or hypotensive animals, as there is a risk of increased renal toxicity. Concurrent administration of potentially nephrotoxic drugs should be avoided.

Use this product under strict veterinary monitoring where there is a risk of gastro-intestinal bleeding, or if the animal previously displayed intolerance to NSAIDs. The treatment should be discontinued if any of these signs are observed: repeated diarrhoea, vomiting, faecal occult blood, sudden weight loss, anorexia, lethargy, degradation of renal or hepatic biochemistry parameters.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash hands after use of the product.
In case of accidental ingestion, seek medical advice immediately and show the package insert or the label to the physician.
Divided tablets should be returned to the original package.

Pregnancy and lactation:
Do not use in pregnant or lactating bitches.
Laboratory studies in rabbits have shown evidence of maternotoxic and foetotoxic effects at dose rates approximating the recommended treatment dose for the dog.

Interaction with other medicinal products and other forms of interaction:
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 for at least 24 hours before the commencement of treatment with Previcox. The treatment-free period, however, should take into account the pharmacokinetic properties of the products used previously.

Previcox must not be administered in conjunction with other NSAIDs or glucocorticosteroids. Gastrointestinal tract ulceration may be exacerbated by corticosteroids in animals given non-steroidal anti-inflammatory drugs.

Concomitant treatment with molecules displaying action on renal flow, e.g. diuretics or Angiotensin Converting Enzyme (ACE) inhibitors, should be subject to clinical monitoring. Concurrent administration of potentially nephrotoxic drugs should be avoided as there might be an increased risk for renal toxicity. As anaesthetic drugs may affect renal perfusion, the use of parenteral fluid therapy during surgery should be considered to decrease potential renal complications when using NSAIDs peri-operatively.

Concurrent use of other active substances that have a high degree of protein binding may compete with firocoxib for binding and thus lead to toxic effects.

Overdose (symptoms, emergency procedures, antidotes):
In dogs ten weeks of age at the start of treatment at dose rates equal or greater to 25 mg/kg/day (5 times the recommended dose) for three months, the following signs of toxicity were observed: bodyweight loss, poor appetite, changes in the liver (accumulation of lipid), brain (vacuolisation), duodenum (ulcers) and death. At dose rates equal or greater to 15 mg/kg/day (3 times the recommended dose) for six months, similar clinical signs were observed, albeit that the severity and frequency were less and duodenal ulcers were absent.
In those target animal safety studies, clinical signs of toxicity were reversible in some dogs following cessation of therapy.

In dogs seven months of age at the start of treatment at dose rates greater than or equal to 25 mg/kg/day (5 times the recommended dose) for six months, gastrointestinal adverse effects, i.e. vomiting were observed.

Overdose studies were not conducted in animals over 14 months of age.

If clinical signs of overdosing are observed, discontinue treatment.

Incompatibilities:
Not applicable.

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

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

Mode of action:
Firocoxib is a non-steroidal anti-inflammatory drug (NSAID) that acts by selective inhibition of cyclooxygenase-2 (COX-2) – mediated prostaglandin synthesis. COX-2 is the isoform of the enzyme that has been postulated to be primarily responsible for the synthesis of prostanoid mediators of pain, inflammation, and fever. In *in-vitro* canine whole blood assays, firocoxib exhibited approximately 380-fold selectivity for COX-2 over COX-1.

Previcox chewable tablets are scored to facilitate accurate dosing and contain caramel and smoke flavours to facilitate administration to dogs.
The chewable tablets (57 mg or 227 mg) are available in the following pack sizes:

- 1 cardboard box containing 1 blister of 10 tablets (10 tablets).
- 1 cardboard box containing 3 blisters of 10 tablets (30 tablets).
- 1 cardboard box containing 18 blisters of 10 tablets (180 tablets).
- 1 cardboard box containing 1 bottle of 60 tablets.

Not all pack sizes may be marketed.