ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EQUIOXX 8.2 mg/g oral paste for horses.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each syringe contains 7.32 g of paste and delivers:

Firocoxib 8.2 mg/g

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral paste.
White to off-white paste.

4. CLINICAL PARTICULARS

4.1 Target species

Horses.

4.2 Indications for use, specifying the target species

Alleviation of pain and inflammation associated with osteoarthritis and reduction of associated lameness in horses.

4.3 Contraindications

Do not use in animals suffering from gastrointestinal disorders and haemorrhage, impaired hepatic, cardiac or renal function and bleeding disorders.
Do not use in breeding, pregnant or lactating animals (see section 4.7).
Do not use concomitantly with corticosteroids or other non-steroidal anti-inflammatory drugs (NSAIDs) (see section 4.8).
Do not use in case of hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Do not use in animals less than 10 weeks. If side effects occur, treatment should be discontinued and the advice of a veterinarian should be sought. Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there may be potential risk of increased renal toxicity. Concurrent administration of potentially nephrotoxic veterinary medicinal products should be avoided.

The recommended treatment dose and duration should not be exceeded.

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

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Avoid contact with eyes and skin. If it occurs, rinse affected area immediately with water.
Wash hands after use of the veterinary medicinal product.
Like other medicinal products that inhibit COX-2, pregnant women or women attempting to conceive should avoid contact with, or wear disposable gloves, when administering the veterinary medicinal product.

4.6 Adverse reactions (frequency and seriousness)

Lesions (erosion/ulceration) of the oral mucosa and of the skin around the mouth were very commonly observed in treated animals during tolerance studies. These lesions were mild and resolved without treatment. Salivation and labial and tongue oedema have been uncommonly associated with the oral lesions in a field study.

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, including isolated reports treated)

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4.7 Use during pregnancy, lactation or lay

No data is available in horses. However, studies with laboratory animals have shown embryofoetotoxicity, malformations, delayed parturition and decreased pup survival. Therefore, do not use in breeding, pregnant or lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

Other NSAIDs, diuretic and substances with high protein binding may compete for binding and lead to toxic effects. Do not use concomitantly with corticosteroids or other NSAIDs.

Pre-treatment with other anti-inflammatory substances may result in additional or increased adverse effects and a treatment-free period with such medicinal products should therefore be observed. The treatment-free period should take into account the pharmacological properties of the medicinal products used previously.

Concomitant treatment with molecules displaying action on renal flow (e.g. diuretics) should be subject to clinical monitoring. Concurrent administration of potentially nephrotoxic medicinal products should be avoided as there might be an increased risk of renal toxicity.

4.9 Amounts to be administered and administration route

Oral use.

Administer 0.1 mg firocoxib per kg bodyweight, once daily. Duration of treatment will be dependent on the response observed, but should not exceed 14 days.

To administer EQUIOXX at the dose of 0.1 mg firocoxib/kg, set the syringe plunger to the appropriate dose division for the horse’s weight. Each full dose division on the syringe plunger delivers sufficient

firocoxib to treat 100 kg body weight. The contents of one syringe will treat horses weighing up to 600 kg. To ensure correct dosage, bodyweight should be determined as accurately as possible to avoid overdosing.

To deliver firocoxib at the appropriate dosage, unlock the knurled ring on the syringe plunger by rotating it ¼ turn and slide it along the plunger shaft to the appropriate dose division for the horse's weight. Rotate the plunger ring ¼ turn to lock it in place and ensure it is locked.

Make sure the horse's mouth contains no feed. Remove the cover from the tip of the syringe. Insert the syringe tip into the horse's mouth at the interdental space and deposit the paste on the base of the tongue.

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

Lesions (erosion/ulceration) of the oral mucosa and of the skin around the mouth may occasionally be observed in treated animals when administered the recommended treatment dose. Typically, these lesions are mild and resolve without treatment, but oral lesions may be associated with salivation and labial and tongue oedema. The incidence of oral/skin lesions increases with increasing dose.

At high dosages and prolonged treatment (3 times the recommended dose for 42 consecutive days and 2.5 times the recommended dose for 92 consecutive days administered once daily) mild to moderate renal lesions were observed. If clinical signs occur, treatment should be discontinued and symptomatic treatment initiated.

4.11 Withdrawal period(s)

Meat and offal: 26 days.
Not authorized for use in animals producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anti-inflammatory and anti-rheumatic products, non-steroids, ATC vet 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*" equine whole blood assays, firocoxib exhibits 222 to 643 fold selectivity for COX-2 over COX-1. The concentration of firocoxib required to inhibit 50% of the COX-2 enzyme (i.e., the IC50) is 0.0369 to 0.12 µM, whereas the IC50 for COX-1 is 20.14 to 33.1 µM.

5.2 Pharmacokinetic particulars

Following oral administration in horses at the recommended dose of 0.1 mg per kg of bodyweight, firocoxib is rapidly absorbed, and the time to maximal concentration (T_{max}) is 3.9 (± 4.4) hours. The peak concentration (C_{max}) is 0.075 (± 0.033) µg/ml (equivalent to approximately 0.223 µM), area

under the curve (AUC_{0-24}) is 0.96 (± 0.26) µg x hr/ml, and oral bioavailability is 79 (± 31) percent. The elimination half-life ($t_{½}$) after a single dose is 29.6 (± 7.5) hours and 50.6 hours after 14 days of dosing. Firocoxib is approximately 97% bound to plasma proteins. Following multiple oral administrations, the steady state is reached by approximately the eighth daily dose. Firocoxib is metabolised predominantly by dealkylation and glucuronidation in the liver. Elimination is principally in the excreta (primarily the urine), with some biliary excretion also observed.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Titanium dioxide (E 171)
Glycerol triacetate
Silica, colloidal anhydrous
Magnesium carbonate, heavy Macrogol
300

6.2 Major incompatibilities

Not applicable.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the syringe: 3 months.

6.4 Special precautions for storage

Replace cap after use.
This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

Pre-filled oral syringe made of polypropylene, with a polyethylene cap, a rubber rod tip, and a polypropylene plunger rod.

Each syringe contains a net weight of 7.32 g of oral paste and is labelled in 100 kg dosing increments.

The oral paste is available in the following pack sizes:
- 1 carton box containing 1 syringe
- 1 carton box containing 7 syringes
- 1 carton box containing 14 syringes

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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

Audevard
42-46 rue Médéric
92110, Clichy
France

8. MARKETING AUTHORISATION NUMBER

EU/2/08/083/001
EU/2/08/083/004 EU/2/08/083/005

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25/06/2008
Date of last renewal: 06/06/2013

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.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EQUIOXX 20 mg/ml solution for injection for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml of the solution contains:

Active substance:
Firocoxib 20 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection

Clear colourless solution

4. CLINICAL PARTICULARS

4.1 Target species

Horses

4.2 Indications for use, specifying the target species

Alleviation of pain and inflammation associated with osteoarthritis and reduction of associated lameness in horses.

4.3 Contraindications

Do not use in animals suffering from gastrointestinal disorders and haemorrhage, impaired hepatic, cardiac or renal function and bleeding disorders.
Do not use in breeding, pregnant or lactating animals (see section 4.7).
Do not use concomitantly with corticosteroids or other non-steroidal anti-inflammatory drugs (NSAIDs) (see section 4.8).
Do not use in case of hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Do not use in animals less than 10 weeks of age.
Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there may be potential risk of increased renal toxicity. Concurrent administration of potentially nephrotoxic veterinary medicinal products should be avoided. Do not exceed the recommended dose or duration of treatment.

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

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
Avoid contact with eyes and skin. If this occurs, rinse affected area immediately with water.
Wash hands after use of the veterinary medicinal product.
Like other medicinal products that inhibit COX-2, pregnant women or women attempting to conceive should avoid contact with, or wear disposable gloves, when administering the veterinary medicinal product.

4.6 Adverse reactions (frequency and seriousness)

Mild reactions at the injection site characterised by swelling and associated with perivascular inflammation have been reported in clinical studies following administration of the product at the recommended dose. There is potential for the injection site reaction to be associated with pain.

Lesions (erosion/ulceration) of the oral mucosa and of the skin around the mouth were very commonly observed in treated animals during tolerance studies. These lesions were mild and resolved without treatment. Salivation and labial and tongue oedema have been uncommonly associated with the oral lesions in a field study.
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, including isolated reports treated)

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product for use in breeding, pregnant or lactating horses has not been evaluated**.** However, studies with laboratory animals have shown embryo-foetotoxicity, malformations, delayed parturition and decreased pup survival. Therefore, do not use in breeding, pregnant or lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

Other NSAIDs, diuretics and substances that have a high degree of protein binding may compete for binding and lead to toxic effects. Do not use concomitantly with corticosteroids or other NSAIDs.

Pre-treatment with other anti-inflammatory substances may result in additional or increased adverse reactions and a treatment-free period with such medicinal products should therefore be observed. The treatment-free period should take into account the pharmacological properties of the medicinal products used previously.

Concurrent administration of potentially nephrotoxic medicinal products should be avoided as there might be an increased risk of renal toxicity. Concomitant treatment with molecules displaying action on renal flow (e.g. diuretics) should be subject to clinical monitoring.

4.9 Amounts to be administered and administration route

The recommended dose is 0.09 mg firocoxib per kg bodyweight (equivalent to 1ml of the solution per 225 kg bodyweight) once daily by intravenous injection.

EQUIOXX 8.2 mg/g Oral Paste may be used for continuation of treatment at a dosage of 0.1 mg firocoxib per kg bodyweight once daily.
The overall duration of treatment with EQUIOXX solution for injection or EQUIOXX oral paste will be dependent on the response observed, but should not exceed 14 days.

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

Lesions (erosion/ulceration) of the oral mucosa and of the skin around the mouth may occasionally be observed in treated animals when administered the recommended treatment dose. Typically, these lesions are mild and resolve without treatment, but oral lesions may be associated with salivation and labial and tongue oedema. The incidence of oral/skin lesions increases with increasing dose.

At high dosages and prolonged treatment (3 times the recommended dose for 42 consecutive days and 2.5 times the recommended dose for 92 consecutive days administered once daily) mild to moderate renal lesions were observed. If clinical signs occur, treatment should be discontinued and symptomatic treatment initiated.

4.11 Withdrawal period(s)

Meat and offal: 26 days
Not authorized for use in animals producing milk for human consumption.

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*" equine whole blood assays, firocoxib exhibits 222 to 643 fold selectivity for COX-2 over COX-1. The concentration of firocoxib required to inhibit 50% of the COX-2 enzyme (i.e., the IC50) is 0.0369 to 0.12 μM, whereas the IC50 for COX-1 is 20.14 to 33.1 μM.

5.2 Pharmacokinetic particulars

The peak plasma levels observed one minute following firocoxib intravenous administration was approximately 3.7 fold greater than the observed peak plasma concentrations reached after administration of the oral paste (oral T_{max} = 2.02 hours). The terminal elimination half-life ($t_{½}$ el) values were not significantly different ($p>0.05$), with mean values of 31.5 hours and 33.0 hours for the oral paste and the intravenous solution, respectively. Firocoxib is approximately 97% bound to plasma proteins. Drug accumulation occurs with repeated dose administrations and steady state concentrations are achieved after 6-8 days of treatment in the horse. Firocoxib is metabolised predominantly by dealkylation and glucuronidation in the liver. Elimination is principally in the excreta (primarily the urine), with some biliary excretion also observed.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol formal
Disodium edetate n-Propyl
gallate Thiodipropionic
acid
Macrogol 400

6.2 Major incompatibilities

In the absence of compatibility studies this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 1 month.

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

Multi-dose amber-coloured glass injection vials closed with rubber stopper and sealed with an aluminium crimped top.

The injection vials are available in the following pack sizes:
- carton containing one vial of 25 ml.
- carton containing 6 vials of 25 ml

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

Audevard
42-46 rue Médéric
92110, Clichy
France

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/08/083/002-003

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25/06/2008
Date of last renewal: 06/06/2013

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.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EQUIOXX 57 mg chewable tablets for horses firocoxib

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains:

Active substance:

Firocoxib 57 mg

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Chewable tablets.
Brown, round, convex, scored tablets.
Tablets are engraved on one side with “M” above the score and “57” below the score.

4. CLINICAL PARTICULARS

4.1 Target species

Horses (450–600 kg)

4.2 Indications for use, specifying the target species

Alleviation of pain and inflammation associated with osteoarthritis and reduction of associated lameness in horses.

4.3 Contraindications

Do not use in animals suffering from gastrointestinal disorders and haemorrhage, impaired hepatic, cardiac or renal function and bleeding disorders.
Do not use in breeding, pregnant or lactating animals (see section 4.7).
Do not use concomitantly with corticosteroids or other non-steroidal anti-inflammatory drugs (NSAIDs) (see section 4.8).
Do not use in case of hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Do not exceed the recommended dosage.

For safe and effective use, this product should only be administered to horses in the weight range 450-600 kg. For horses weighing under 450 kg or over 600 kg, and where firocoxib is the treatment of choice, use of other firocoxib-containing formulations that allow for accurate dosing is advised.
Avoid use in any dehydrated, hypovolaemic or hypotensive animals, as there may be potential risk of increased renal toxicity. Concurrent administration of potentially nephrotoxic veterinary medicinal products should be avoided. The recommended treatment dose and duration should not be exceeded.

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

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands after use of the veterinary medicinal product.

4.6 Adverse reactions (frequency and seriousness)

Lesions (erosion/ulceration) of the oral mucosa and of the skin around the mouth were very commonly observed in treated animals during tolerance studies. These lesions were mild and resolved without treatment. Salivation and labial and tongue oedema have been uncommonly associated with the oral lesions in a field study.

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, including isolated reports treated)

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product for use in breeding, pregnant or lactating horses has not been established. Laboratory studies in laboratory animals have shown evidence of embryofoetotoxicity, malformations, delayed parturition and decreased pup survival. Do not use in breeding, pregnant or lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

Other NSAIDs, diuretic and substances with high protein binding may compete for binding and lead to toxic effects. Do not use concomitantly with corticosteroids or other NSAIDs.

Pre-treatment with other anti-inflammatory substances may result in additional or increased adverse effects and a treatment-free period with such medicinal products should therefore be observed. The treatment-free period should take into account the pharmacological properties of the medicinal products used previously.

Concomitant treatment with molecules displaying action on renal flow (e.g. diuretics) should be subject to clinical monitoring. Concurrent administration of potentially nephrotoxic medicinal products should be avoided as there might be an increased risk of renal toxicity.

4.9 Amounts to be administered and administration route

Oral use.

Administer one tablet once daily for horses weighing 450–600 kg bodyweight.
Duration of treatment will be dependent on the response observed, but should not exceed 14 days.

One tablet should be administered with a small amount of food in a bucket or direct by hand, presenting the tablet combined with a small amount of food or with a treat in the palm of the hand. After administration, it is recommended to examine the buccal cavity to ensure that the tablet has been adequately swallowed.

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

At high dosages and prolonged treatment (3 times the recommended dose for 42 consecutive days and 2.5 times the recommended dose for 92 consecutive days administered once daily) mild to moderate renal lesions were observed. If clinical signs occur, treatment should be discontinued and symptomatic treatment initiated.
The incidence of oral/skin lesions increases with increasing dose.

4.11 Withdrawal period(s)

Meat and offal: 26 days.
Not authorized for use in animals producing milk for human consumption.

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*” equine whole blood assays, firocoxib exhibits 222 to 643 fold selectivity for COX-2 over COX-1. The concentration of firocoxib required to inhibit 50% of the COX-2 enzyme (i.e., the IC50) is 0.0369 to 0.12 μM, whereas the IC50 for COX-1 is 20.14 to 33.1 μM.

5.2 Pharmacokinetic particulars

Following oral administration in horses at the recommended dose of 1 tablet per horses, firocoxib is rapidly absorbed, and the time to maximal concentration (T_{max}) is 2.43 (± 2,17) hours. The peak concentration (C_{max}) is 0.075 (± 0.021) μg/ml, area under the curve ($AUC_{0\text{-}inf}$) is 3.48 (± 1.15) μg x hr/ml. The elimination half-life ($t_{½}$) after a single dose is 38.7 (± 7.8) hours. Firocoxib is approximately 97% bound to plasma proteins. Following multiple oral administrations, the steady state is reached by approximately the eighth daily dose. Firocoxib is metabolised predominantly by dealkylation and glucuronidation in the liver. Elimination is principally in the excreta (primarily the urine), with some biliary excretion also observed.

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.

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

The chewable tablets are available in the following pack sizes:

- 1 cardboard box containing 10 tablets in transparent PVC /aluminium foil blisters.
- 1 cardboard box containing 30 tablets in transparent PVC /aluminium foil blisters.
- 1 cardboard box containing 180 tablets in transparent PVC /aluminium foil blisters. - 1 cardboard box containing 60 tablets in a 30 ml high density polyethylene bottle.

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 product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Audevard
42-46 rue Médéric
92110, Clichy
France

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/08/083/006-009

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25/06/2008
Date of last renewal: 06/06/2013

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 OR 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:

Merial Toulouse
4 Chemin du Calquet
31000 Toulouse
France

Ceva Santé Animale
10, av. de La Ballastière
33500 Libourne
France

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

The active substance in EQUIOXX 8.2 mg/g oral paste for horses, EQUIOXX 20 mg/ml solution for injection for horses and EQUIOXX 57 mg chewable tablets for horses is an allowed substance as described in table 1 of the annex to Commission Regulation (EU) No 37/2010 as follows:

Pharmacologically active substance	**Marker residue**	**Animal species**	**MRL**	**Target tissues**	**Other provisions**	**Therapeutic classification**
Firocoxib	Firocoxib	Equidae	10 µg/kg 15 µg/kg 60 µg/kg 10 µg/kg	Muscle Fat Liver Kidney	No entry	Antiinflammatory agents/ Nonsteroidal antiinflammatory agents

- EQUIOXX 8.2 mg/g oral paste for horses

The excipients listed in section 6.1 of the SPC are allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required.

- EQUIOXX 20 mg/ml solution for injection for horses

The excipients listed in section 6.1 of the SPC (Glycerol formal and Macrogol 400) are allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required.
Disodium EDTA, n-propyl gallate, and thiodipropionic acid, are used to stabilize the glycerol formal and therefore are not considered as excipients in the context of MRLs.

- EQUIOXX 57 mg chewable tablets for horses

The excipients listed in section 6.1 of the SPC are allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required.

D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

The periodic safety update report (PSUR) cycle should be restarted for submission of 6 monthly reports (covering all authorised presentations of the product) for the next two years, followed by yearly reports for the subsequent two years and thereafter at 3 yearly intervals.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE Carton box labelling

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EQUIOXX 8.2 mg/g oral paste .
Firocoxib

2. STATEMENT OF ACTIVE SUBSTANCES

Firocoxib 8.2 mg/g

3. PHARMACEUTICAL FORM

Oral paste.

4. PACKAGE SIZE

1 syringe.
7 syringes.
14 syringes.

5. TARGET SPECIES

For horses.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Meat and offal: 26 days.
Do not use in mares producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened, use within 3 months

11. SPECIAL STORAGE CONDITIONS

Replace cap after use.

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

Disposal: read the 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

Audevard
42-46 rue Médéric
92110, Clichy
France

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/08/083/001 EU/2/08/083/004
EU/2/08/083/005

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
Syringe labelling

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EQUIOXX 8.2 mg/g oral paste for horses
Firocoxib

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Firocoxib 8.2 mg/g

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

7.32 g of oral paste

4. ROUTE(S) OF ADMINISTRATION

Oral use.

5. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Meat and offal: 26 days.
Do not use in mares producing milk for human consumption.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Once opened use within 3 months.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE Carton Box labelling

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EQUIOXX 20 mg/ml solution for injection
Firocoxib

2. STATEMENT OF ACTIVE SUBSTANCES

Firocoxib 20 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

25 ml
6 x 25 ml

5. TARGET SPECIES

For horses

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intravenous use
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Meat and offal: 26 days
Do not use in mares producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached use within 1 month.

11. SPECIAL STORAGE CONDITIONS

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

Disposal: read the 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

Audevard
42-46 rue Médéric
92110, Clichy
France

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/08/083/002
EU/2/08/083/003

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
Vial labelling – 25 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EQUIOXX 20 mg/ml solution for injection for horses
Firocoxib

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Firocoxib 20 mg/ml

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

25 ml

4. ROUTE(S) OF ADMINISTRATION

IV

5. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Meat and offal: 26 days.
Do not use in mares producing milk for human consumption.

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP
Once broached use within 1 month.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EQUIOXX 57 mg chewable tablet for horses firocoxib

2. STATEMENT OF ACTIVE SUBSTANCES

Firocoxib 57 mg

3. PHARMACEUTICAL FORM

Chewable tablet

4. PACKAGE SIZE

10 tablets
30 tablets 60 tablets
180 tablets

5. TARGET SPECIES

For horses (450–600 kg)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Meat and offal: 26 days.
Do not use in mares producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Only for horses weighing 450–600 kg.
Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 30 °C.

12. SPECIAL 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

Audevard
42-46 rue Médéric
92110, Clichy
France

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/08/083/006 10 tablets EU/2/08/083/007
30 tablets
EU/2/08/083/008 180 tablets
EU/2/08/083/009 60 tablets

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
Bottle label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EQUIOXX 57 mg chewable tablet for horses firocoxib

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Firocoxib 57 mg

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

60 tablets

4. ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

5. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Meat and offal: 26 days.
Do not use in mares producing milk for human consumption.

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 BLISTERS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EQUIOXX 57 mg chewable tablets firocoxib

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Audevard

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
EQUIOXX 8.2 mg/g oral paste for horses

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

Marketing authorisation holder:
Audevard
42-46 rue Médéric
92110, Clichy
France

Manufacturer responsible for batch release:
MERIAL
4 chemin du Calquet
31000 Toulouse France.

Ceva Santé Animale
10, av. de La Ballastière
33500 Libourne
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

EQUIOXX 8.2 mg/g oral paste for horses.

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Firocoxib 8.2 mg/g

4. INDICATIONS

Alleviation of pain and inflammation associated with osteoarthritis and reduction of associated lameness in horses.

5. CONTRAINDICATIONS

Do not use in animals suffering from gastrointestinal disorders and haemorrhage, impaired hepatic, cardiac or renal function and bleeding disorders.
Do not use in breeding, pregnant or lactating animals.
Do not use concomitantly with corticosteroids or other NSAIDs.

6. ADVERSE REACTIONS

Lesions (erosion/ulceration) of the oral mucosa and of the skin around the mouth were very commonly observed in treated animals during tolerance studies. These lesions were mild and resolved without treatment. Salivation and labial and tongue oedema have been uncommonly associated with the oral lesions in a field study.

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, including isolated reports treated)

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

Horses.

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

0.1 mg firocoxib per kg bodyweight, once daily for up to 14 days. Oral use.

9. ADVICE ON CORRECT ADMINISTRATION

To administer EQUIOXX at the dose of 0.1 mg firocoxib/kg, set the syringe plunger to the appropriate dose division for the horse's weight. Each full dose division on the syringe plunger delivers sufficient firocoxib to treat 100 kg body weight. The contents of one syringe will treat horses weighing up to 600 kg. To ensure correct dosage, bodyweight should be determined as accurately as possible to avoid overdosing.

To deliver firocoxib at the appropriate dosage, unlock the knurled ring on the syringe plunger by rotating it ¼ turn and slide it along the plunger shaft to the appropriate dose division for the horse's weight. Rotate the plunger ring ¼ turn to lock it in place and ensure it is locked.

Make sure the horse's mouth contains no feed. Remove the cover from the tip of the syringe. Insert the syringe tip into the horse's mouth at the interdental space and deposit the paste on the base of the tongue.

10. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Meat and offal: 26 days.
Not authorized for use in animals producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Replace cap after use.
Do not use after the expiry date stated on the label.
Shelf-life after first opening the syringe: 3 months.

12. SPECIAL WARNINGS

Special warnings for each target species:
If side effects occur, treatment should be discontinued and the advice of a veterinarian should be sought. Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there may be potential risk of increased renal toxicity. Concurrent administration of potentially nephrotoxic drugs should be avoided.

Do not use in animals less than 10 weeks.
The recommended treatment dose and duration should not be exceeded.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Avoid contact with eyes and skin. If it occurs, rinse affected area immediately with water. Wash hands after use of the product.
Like other medicinal products that inhibit COX-2, pregnant women or women attempting to conceive should avoid contact with, or wear disposable gloves, when administering the product.

Pregnancy and lactation:
No data on use during pregnancy is available in horses. Therefore, do not use in breeding, pregnant or lactating animals.

Interaction with other medicinal products and other forms of interaction:
Other NSAIDs, diuretic and substances with high protein binding may compete for binding and lead to toxic effects. Do not use concomitantly with corticosteroids or other NSAIDs.
Pre-treatment with other anti-inflammatory substances may result in additional or increased adverse effects and a treatment-free period with such products should therefore be observed. The treatmentfree period should take into account the pharmacological properties of the products used previously.

Concomitant treatment with molecules displaying action on renal flow (e.g. diuretics) 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.

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

15. OTHER INFORMATION

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.
The oral paste is available in the following pack sizes:

- 1 carton box containing 1 syringe
- 1 carton box containing 7 syringes
- 1 carton box containing 14 syringes

Not all pack sizes may be marketed.

PACKAGE LEAFLET:
EQUIOXX 20 mg/ml solution for injection for horses

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

Marketing authorisation holder :
Audevard
42-46 rue Médéric
92110, Clichy
France

Manufacturer responsible for batch release:
MERIAL
4, Chemin du Calquet
31000 Toulouse Cedex
France

Ceva Santé Animale
10, av. de La Ballastière
33500 Libourne
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

EQUIOXX 20 mg/ml solution for injection for horses.

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

Firocoxib 20 mg/ml

4. INDICATION(S)

Alleviation of pain and inflammation associated with osteoarthritis and reduction of associated lameness in horses.

5. CONTRAINDICATIONS

Do not use in animals suffering from gastrointestinal disorders and haemorrhage, impaired hepatic, cardiac or renal function and bleeding disorders. Do not use in breeding, pregnant or lactating animals.
Do not use concomitantly with corticosteroids or other non-steroidal anti-inflammatory drugs (NSAIDs).
Do not use in case of hypersensitivity to the active substance or to any of the excipients**.**

6. ADVERSE REACTIONS

Mild injection site swellings associated with perivascular inflammation and pain.
Lesions (erosion/ulceration) of the oral mucosa and of the skin around the mouth were very commonly observed in treated animals during tolerance studies. These lesions were mild and resolved without treatment. Salivation and labial and tongue oedema have been uncommonly associated with the oral lesions in a field study.
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, including isolated reports treated)

At high dosages and prolonged treatment (3 times the recommended dose for 42 consecutive days and 2.5 times the recommended dose for 92 consecutive days administered once daily) mild to moderate renal lesions were observed. If clinical signs occur, treatment should be discontinued and symptomatic treatment initiated.

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

Horses

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

The recommended dose is 0.09 mg firocoxib per kg bodyweight (equivalent to 1 ml of the solution per 225 kg bodyweight) once daily by intravenous injection.
EQUIOXX 8.2 mg/g Oral Paste may be used for continuation of treatment at a dosage of 0.1 mg firocoxib per kg bodyweight once daily.
The overall duration of treatment with EQUIOXX solution for injection or EQUIOXX oral paste will be dependent on the response observed, but should not exceed 14 days.

9. ADVICE ON CORRECT ADMINISTRATION

Avoid the introduction of contamination during use.

10. WITHDRAWAL PERIOD(S)

Meat and offal: 26 days.
Not authorized for use in animals producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Do not use after the expiry date stated on the label after EXP. Shelflife
after first opening the container : 1 month.

12. SPECIAL WARNING(S)

Special warnings for each target species:
If side effects occur, treatment should be discontinued and the advice of a veterinarian should be sought. Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there may be potential risk of increased renal toxicity. Concurrent administration of potentially nephrotoxic medicinal drugs should be avoided.

Do not use in animals less than 10 weeks of age.
Do not exceed the recommended dose or duration of treatment.
Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
Avoid contact with eyes and skin. If this occurs, rinse affected area immediately with water.
Wash hands after use of the product.
Like other medicinal products that inhibit COX-2, pregnant women or women attempting to conceive should avoid contact with, or wear disposable gloves, when administering the product.

Pregnancy and lactation:
The safety of the product for use in breeding, pregnant or lactating horses has not been evaluated. Therefore, do not use in breeding, pregnant or lactating animals.

Interaction with other medicinal products and other forms of interaction:
Other NSAIDs, diuretics and substances that have a high degree of protein binding may compete for binding and lead to toxic effects. Do not use concomitantly with corticosteroids or other NSAIDs. Pre-treatment with other anti-inflammatory substances may result in additional or increased adverse reactions and a treatment-free period with such products should therefore be observed. The treatmentfree period should take into account the pharmacological properties of the products used previously.

Concurrent administration of potentially nephrotoxic drugs should be avoided, as there might be an increased risk of renal toxicity. Concomitant treatment with molecules displaying action on renal flow (e.g. diuretics) should be subject to clinical monitoring.

In the absence of compatibility studies this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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 veterinary medicinal 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* equine whole blood assays, firocoxib exhibited 222 to 643 fold selectivity for COX-2 over COX-1.

The injection vials are available in the following pack sizes:
- carton containing one vial of 25 ml.
- carton containing 6 vials of 25 ml

Not all pack sizes may be marketed.

PACKAGE LEAFLET:
EQUIOXX 57 mg chewable tablets for horses

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

Marketing authorisation holder:
Audevard
42-46 rue Médéric
92110, Clichy
France

Manufacturer responsible for batch release:
MERIAL
4 chemin du Calquet
31000 Toulouse
France

Ceva Santé Animale
10, av. de La Ballastière
33500 Libourne
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

EQUIOXX 57 mg chewable tablets for horses.
firocoxib

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Firocoxib 57 mg
Brown, round, convex, scored tablets.
Tablets are engraved on one side with “M” above the score and “57” below the score.

4. INDICATIONS

Alleviation of pain and inflammation associated with osteoarthritis and reduction of associated lameness in horses weighing between 450 kg and 600 kg bodyweight.

5. CONTRAINDICATIONS

Do not use in animals suffering from gastrointestinal disorders and haemorrhage, impaired hepatic, cardiac or renal function and bleeding disorders.
Do not use in breeding, pregnant or lactating animals.
Do not use concomitantly with corticosteroids or other NSAIDs.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

Lesions (erosion/ulceration) of the oral mucosa and of the skin around the mouth were very commonly observed in treated animals during tolerance studies. These lesions were mild and resolved without treatment. Salivation and labial and tongue oedema have been uncommonly associated with the oral lesions in a field study.
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, including isolated reports treated)

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

Horses (450–600 kg).

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

Oral use.
Administer one tablet once daily for horses weighing 450–600 kg bodyweight.

Duration of treatment will be dependent on the response observed, but should not exceed 14 days.

9. ADVICE ON CORRECT ADMINISTRATION

One tablet should be administered with a small amount of food in a bucket or direct by hand, presenting the tablet combined with a small amount of food or with a treat in the palm of the hand.
After administration, it is recommended to examine the buccal cavity to ensure that the tablet has been adequately swallowed.
Do not exceed the recommended dosage.
For safe and effective use, this product should only be administered to horses in the weight range 450-600 kg. For horses weighing under 450 kg or over 600 kg, and where firocoxib is the treatment of choice, use of other firocoxib-containing formulations that allow for accurate dosing is advised.

10. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Meat and offal: 26 days.
Not authorized for use in animals producing milk for human consumption.

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 stated on the label after EXP.

12. SPECIAL WARNINGS

Special warnings for each target species:
If side effects occur, treatment should be discontinued and the advice of a veterinarian should be sought. Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there may be potential risk of increased renal toxicity. Concurrent administration of potentially nephrotoxic drugs should be avoided.
The recommended treatment dose and duration should not be exceeded.

Special precautions to be taken by the person administering the veterinary medicinal product to animals.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands after use of the veterinary medicinal product.
Like other medicinal products that inhibit COX-2, pregnant women or women attempting to conceive should avoid contact with, or wear disposable gloves, when administering the product.

Pregnancy and lactation:
No data on use during pregnancy is available in horses. Therefore, do not use in breeding, pregnant or lactating animals.

Interaction with other medicinal products and other forms of interaction:
Other NSAIDs, diuretic and substances with high protein binding may compete for binding and lead to toxic effects. Do not use concomitantly with corticosteroids or other NSAIDs.
Pre-treatment with other anti-inflammatory substances may result in additional or increased adverse effects and a treatment-free period with such products should therefore be observed. The treatmentfree period should take into account the pharmacological properties of the products used previously.

Concomitant treatment with molecules displaying action on renal flow (e.g. diuretics) 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.

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 veterinary medicinal 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* equine whole blood assays, firocoxib exhibited 222 to 643 fold selectivity for COX-2 over COX-1.

The 57 mg chewable tablets are available in the following pack sizes:

- 1 cardboard box containing 10 tablets in blisters
- 1 cardboard box containing 30 tablets in blisters
- 1 cardboard box containing 180 tablets in blisters
- 1 cardboard box containing 60 tablets in a 30 ml bottle

Not all pack sizes may be marketed.