

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 delivers:

Active substances:

Firocoxib 8.2 mg/g

Excipients:

Qualitative composition of excipients and other constituents
Titanium dioxide (E171)
Glycerol triacetate
Silica, colloidal anhydrous
Magnesium carbonate
Macrogol 300

White to off-white paste.

3. CLINICAL INFORMATION

3.1 Target species

Horses.

3.2 Indications for use for each target species

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

3.3 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 3.7).

Do not use concomitantly with corticosteroids or other non-steroidal anti-inflammatory drugs (NSAIDs) (see section 3.8).

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Horses:

Very common (>1 animal / 10 animals treated):	Ulceration, ¹ Erosion ¹
Uncommon (1 to 10 animals / 1 000 animals treated):	Salivation, ² Lip oedema, ² Tongue oedema ²

¹ Of the oral mucosa and the skin around the mouth. Mild and resolve without treatment.

² Associated with oral lesions.

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

Pregnancy and lactation:

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.

3.8 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.

3.9 Administration routes and dosage

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 the veterinary medicinal product 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.

Replace cap after use.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

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

Meat and offal: 26 days.

Not authorised for use in animals producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QM01AH90.

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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 (AUC₀₋₂₄) is 0.96 (± 0.26) µg x hr/ml, and oral bioavailability is 79 (± 31) percent.

The elimination half-life (t_{1/2}) 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

Shelf life after first opening the immediate packaging: 3 months.

5.3 Special precautions for storage

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

5.4 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.

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

Audevard

7. MARKETING AUTHORISATION NUMBER(S)

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

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 25/06/2008.

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

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 \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

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 substances:

Firocoxib 20 mg

Excipients:

Qualitative composition of excipients and other constituents
Glycerol formal
Disodium edetate
n-Propyl gallate
Thiodipropionic acid
Macrogol 400

Clear colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Horses.

3.2 Indications for use for each target species

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

3.3 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 3.7).

Do not use concomitantly with corticosteroids or other non-steroidal anti-inflammatory drugs (NSAIDs) (see section 3.8).

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Horses:

Very common (>1 animal / 10 animals treated):	Ulceration, ¹ Erosion ¹
Uncommon (1 to 10 animals / 1 000 animals treated):	Salivation, ² Lip oedema, ² Tongue oedema ²
Undetermined frequency (cannot be estimated from the available data):	Injection site swelling ³ Injection site pain.

¹ Of the oral mucosa and the skin around the mouth. Mild and resolve without treatment.

² Associated with oral lesions.

³ Associated with perivascular inflammation.

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

Pregnancy and lactation:

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.

3.8 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.

3.9 Administration routes and dosage

Intravenous use.

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

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

Meat and offal: 26 days.

Not authorised for use in animals producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QM01AH90.

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 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.

5.3 Special precautions for storage

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

5.4 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.

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

Audevard

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/08/083/002-003

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 25/06/2008.

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

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 \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EQUIOXX 57 mg chewable tablets for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains:

Active substances:

Firocoxib 57 mg

Excipients:

Qualitative composition of excipients and other constituents
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)

Brown, round, convex, scored chewable tablets.

Tablets are engraved on one side with “M” above the score and “57” below the score.

3. CLINICAL INFORMATION

3.1 Target species

Horses (450–600 kg).

3.2 Indications for use for each target species

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

3.3 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 3.7).

Do not use concomitantly with corticosteroids or other non-steroidal anti-inflammatory drugs (NSAIDs) (see section 3.8).

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Horses (450–600 kg):

Very common (>1 animal / 10 animals treated):	Ulceration, ¹ Erosion ¹
Uncommon (1 to 10 animals / 1 000 animals treated):	Salivation, ² Lip oedema, ² Tongue oedema ²

¹ Of the oral mucosa and the skin around the mouth. Mild and resolve without treatment.

² Associated with oral lesions.

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

Pregnancy and lactation:

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.

3.8 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.

3.9 Administration routes and dosage

Oral use.

Administer one chewable 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 chewable 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

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

Meat and offal: 26 days.

Not authorised for use in animals producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QM01AH90.

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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-inf}) is 3.48 (± 1.15) µg x hr/ml.

The elimination half-life (t_{1/2}) 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

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

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

The chewable tablets are available in the following pack sizes:

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

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

Audevard

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/08/083/006-010

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 25/06/2008

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

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 \(https://medicines.health.europa.eu/veterinary\)](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

CARTON BOX LABELLING

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EQUIOXX 8.2 mg/g oral paste

2. STATEMENT OF ACTIVE SUBSTANCES

Each syringe contains 7.32 g of paste and delivers:

Firocoxib 8.2 mg/g

3. PACKAGE SIZE

1 syringe
7 syringes
14 syringes

4. TARGET SPECIES

Horses.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

Withdrawal periods:

Meat and offal: 26 days.

Not authorised for use in mares producing milk for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use within 3 months.

9. SPECIAL STORAGE PRECAUTIONS

Replace cap after use.

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

Audevard

14. MARKETING AUTHORISATION NUMBERS

EU/2/08/083/001 1 syringe
EU/2/08/083/004 7 syringes
EU/2/08/083/005 14 syringes

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
SYRINGE LABELLING

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EQUIOXX

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Firocoxib 8.2 mg/g

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 3 months.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX LABELLING

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EQUIOXX 20 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

One ml of the solution contains:

Firocoxib 20 mg

3. PACKAGE SIZE

25 ml

6 x 25 ml

4. TARGET SPECIES

Horses.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intravenous use.

7. WITHDRAWAL PERIODS

Withdrawal periods:

Meat and offal: 26 days.

Not authorised for use in mares producing milk for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 1 month.

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

Audevard

14. MARKETING AUTHORISATION NUMBERS

EU/2/08/083/002 25 ml

EU/2/08/083/003 6 x 25 ml

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL LABELLING – 25 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EQUIOXX

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Firocoxib 20 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 1 month.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EQUIOXX 57 mg chewable tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each chewable tablet contains:

Firocoxib 57 mg

3. PACKAGE SIZE

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

4. TARGET SPECIES

Horses (450–600 kg).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

Withdrawal periods:

Meat and offal: 26 days.

Not authorised for use in mares producing milk for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 30 °C.

Store in the original package.

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

Audevard

14. MARKETING AUTHORISATION NUMBERS

EU/2/08/083/006 10 chewable tablets

EU/2/08/083/007 30 chewable tablets

EU/2/08/083/010 60 chewable tablets (blister)

EU/2/08/083/008 180 chewable tablets

EU/2/08/083/009 60 chewable tablets (bottle)

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
BOTTLE LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EQUIOXX

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Firocoxib 57 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

EQUIOXX



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Firocoxib 57 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

EQUIOXX 8.2 mg/g oral paste for horses

2. Composition

Each syringe contains 7.32 g of paste and delivers:

Active substances:

Firocoxib 8.2 mg/g

White to off-white paste.

3. Target species

Horses.

4. Indications for use

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.

Do not use in cases of hypersensitivity to the active substance or any of the excipients.

6. Special warnings

Special precautions for safe use in the target species:

Do not use in animals less than 10 weeks of age. 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 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 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. However, studies with laboratory animals have shown embryofetotoxicity, malformations, delayed parturition and decreased pup survival. 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 treatment free 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.

Overdose:

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.

7. Adverse events

Horses:

Very common (>1 animal / 10 animals treated):	Ulceration, ¹ Erosion ¹
Uncommon (1 to 10 animals / 1 000 animals treated):	Salivation, ² Lip oedema (swelling), ² Tongue oedema (swelling) ²

¹ Of the oral mucosa and the skin around the mouth. Mild and resolve without treatment.

² Associated with oral lesions.

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 its local representative 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.

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

9. Advice on correct administration

To administer the veterinary medicinal product 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.

Replace cap after use.

10. Withdrawal periods

Meat and offal: 26 days.

Not authorised 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 this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 3 months.

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

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.

15. Date on which the package leaflet was last revised

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse events:

Audevard
37-39 rue de Neuilly
92110 Clichy
France
pvrc@audevard.com
+33 1 47 56 38 26

Manufacturer responsible for batch release:

Boehringer Ingelheim Animal Health
France 4 chemin du Calquet
31000 Toulouse
France

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

17. 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.

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

EQUIOXX 20 mg/ml solution for injection for horses

2. Composition

One ml of the solution contains:

Active substances:

Firocoxib 20 mg

Clear colourless solution.

3. Target species

Horses.

4. Indications for use

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 cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special precautions for safe use in the target species:

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

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 treatment free 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.

Major incompatibilities:

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

Overdose:

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.

7. Adverse events

Horses:

Very common (>1 animal / 10 animals treated):	Ulceration, ¹ Erosion ¹
Uncommon (1 to 10 animals / 1 000 animals treated):	Salivation, ² Lip oedema (swelling), ² Tongue oedema (swelling) ²
Undetermined frequency (cannot be estimated from the available data):	Injection site swelling ³ Injection site pain.

¹ Of the oral mucosa and the skin around the mouth. Mild and resolve without treatment.

² Associated with oral lesions.

³ Associated with perivascular inflammation.

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 its local representative 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

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

10. Withdrawal periods

Meat and offal: 26 days.

Not authorised 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 this veterinary medicinal product after the expiry date which is stated on the label after Exp.

The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 1 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 or pharmacist 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/2/08/083/002-003

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.

15. Date on which the package leaflet was last revised

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse events:

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92110 Clichy
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+33 1 47 56 38 26

Manufacturer responsible for batch release:

Boehringer Ingelheim Animal Health
France 4 chemin du Calquet
31000 Toulouse
France

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

17. Other information

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.

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

EQUIOXX 57 mg chewable tablets for horses

2. Composition

Each chewable tablet contains:

Active substances:

Firocoxib 57 mg

Brown, round, convex, scored tablets.

Tablets are engraved on one side with “M” above the score and “57” below the score.

3. Target species

Horses (450–600 kg).



4. Indications for use

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 cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special precautions for safe use in the 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 treatment free 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.

Overdose:

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.

7. Adverse events

Horses (450–600 kg):

Very common (>1 animal / 10 animals treated):	Ulceration, ¹ Erosion ¹
Uncommon (1 to 10 animals / 1 000 animals treated):	Salivation, ² Lip oedema (swelling), ² Tongue oedema (swelling) ²

¹ Of the oral mucosa and the skin around the mouth. Mild and resolve without treatment.

² Associated with oral lesions.

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 its local representative 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.

Administer one chewable 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 chewable 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 periods

Meat and offal: 26 days.

Not authorised 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 which is stated on the label after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater 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 or pharmacist 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/2/08/083/006-010

The 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 60 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.

15. Date on which the package leaflet was last revised

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse events:

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37-39 rue de Neuilly
92110 Clichy
France
pvrc@audevard.com
+33 1 47 56 38 26

Manufacturer responsible for batch release:

Boehringer Ingelheim Animal Health France
4 chemin du Calquet
31000 Toulouse
France

EYLIO
9 rue des Tuileries
67460 Souffelweyersheim
France

PROVET SA
Thesi Vrago
Aspropyrgos Attiki, 19300
Greece

17. Other information

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.