SUMMARY OF PRODUCT CHARACTERISTICS

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 (Tmax) is 2.43 (± 2,17) hours. The peak concentration (Cmax) is 0.075 (± 0.021) µg/ml, area under the curve (AUC0-inf) is 3.48 (± 1.15) µg x hr/ml. The elimination half-life (t½) 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 60 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
37-38 rue de Neuilly
92110, Clichy
France

8. MARKETING AUTHORISATION NUMBER

Vm 44684/5001

9. DATE OF FIRST AUTHORISATION

09 February 2017

10. DATE OF REVISION OF THE TEXT

August 2023

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

Approved 24 August 2023