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
37-38 rue de Neuilly
92110, Clichy
France

16. MARKETING AUTHORISATION NUMBER(S)

Vm 44684/5001

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

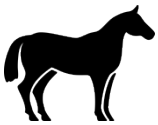
EXP {month/year}

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.

A. PACKAGE LEAFLET

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
37-39 rue de Neuilly
92110, Clichy
France

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

EQUIOXX 57 mg chewable tablets for horses.
firocoxib

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

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. INDICATION(S)

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 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 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

August 2023

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 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.

Approved 24 August 2023