ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

1. 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
37-39 rue de Neuilly
92110, Clichy
France

16. MARKETING AUTHORISATION NUMBER(S)

Vm 44684/5000

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
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.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Equioxx 20 mg/ml solution for injection

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

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

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 associatedlameness 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 commonlyobserved 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 symptomatictreatment initiated.

If you notice any side effects, even those not already listed in this package leaflet or you think that themedicine 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 per225 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 mgfirocoxib per kg bodyweight once daily.
The overall duration of treatment with EQUIOXX solution for injection or EQUIOXX oral paste willbe 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 beavoided.

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 toanimals:
In case of accidental self-injection, seek medical advice immediately and show the package leaflet orthe 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 conceiveshould 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 otherveterinary medicinal products.

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

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures shouldhelp to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

March 2022

Detailed information on this veterinary medicinal product is available on the website of the EuropeanMedicines 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.

Approved 04 March 2022