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 for Horses
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 ORWASTE 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 44684/5002

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

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.

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
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 Ballastière33500 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. 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 NSAIDs.

6. ADVERSE REACTIONS

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)

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 AND METHOD OF ADMINISTRATION

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

9. ADVICE ON CORRECT ADMINISTRATION

To administer EQUIOXX at the dose of 0.1 mg firocoxib/kg, set the syringe plunger to the appropriatedose 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 600kg. 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'sweight. 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 thesyringe 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 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 potentialrisk of increased renal toxicity. Concurrent administration of potentially nephrotoxic drugs should beavoided.

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 toanimals:
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or thelabel to the physician.
Avoid contact with eyes and skin. If it occurs, rinse affected area immediately with water. Washhands 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:
No data on use during pregnancy is available in horses. Therefore, do not use in breeding, pregnant orlactating 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 totoxic effects. Do not use concomitantly with corticosteroids or other NSAIDs.
Pre-treatment with other anti-inflammatory substances may result in additional or increased adverseeffects 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 beavoided as there might be an increased risk of renal

toxicity.

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

Firocoxib is a non-steroidal anti-inflammatory drug (NSAID) belonging to the Coxib group, whichacts 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.

Approved 04 March 2022