# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equioxx 20 mg/ml solution for injection

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml of the solution contains:

**Active substance:**
Firocoxib 20 mg

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Solution for

injection Clear

colourless solution

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Horses

### 4.2 Indications for use, specifying the target species

Alleviation of pain and inflammation associated with osteoarthritis and reduction of associatedlameness 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 use in animals less than 10 weeks of age.
Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there may be potential risk ofincreased 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 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 veterinary medicinal 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 veterinary medicinal product.

## 4.6 Adverse reactions (frequency and seriousness)

Mild reactions at the injection site characterised by swelling and associated with perivascular inflammation have been reported in clinical studies following administration of the product at therecommended dose. There is potential for the injection site reaction to be associated with 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)

## 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 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.

## 4.8 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.

## 4.9 Amounts to be administered and administration route

The recommended dose is 0.09 mg firocoxib per kg bodyweight (equivalent to 1ml 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.

## 4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Lesions (erosion/ulceration) of the oral mucosa and of the skin around the mouth may occasionally be observed in treated animals when administered the recommended treatment dose. Typically, these lesions are mild and resolve without treatment, but oral lesions may be associated with salivation and labial and tongue oedema. 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.

### 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. ATCvetcode: QM01AH90

### 5.1 Pharmacodynamic properties

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.
Cyclooxygenase is responsible for generation of prostaglandins. COX-2 is the isoform of the enzymethat 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

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 theoral 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.

# 6. PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Glycerol formal
Disodium edetate n-
Propylgallate
Thiodipropionic acid
Macrogol 400

## 6.2 Major incompatibilities

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

## 6.3 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.

## 6.4 Special precautions for storage

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

## 6.5 Nature and composition of immediate packaging

Multi-dose amber-coloured glass injection vials closed with rubber stopper and sealed with analuminium 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.

## 6.6 Special precautions for the disposal of unused veterinary medicinal product or wastematerials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinalproducts should be disposed of in accordance with local requirements.

## 7. MARKETING AUTHORISATION HOLDER

AUDEVARD
37-39 rue de Neuilly
92110, Clichy
France

## 8. MARKETING AUTHORISATION NUMBER

Vm 44684/5000

## 9. DATE OF FIRST AUTORISATION

18 December 2009

## 10. DATE OF REVISION OF THE TEXT

March 2022

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

Approved 04 March 2022