[09/2018]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cronyxin 50 mg/g Oral paste for horses (DE, AT, BE, EE, LV, LT, ES, FR, IE, IT, NL, PL, UK)
Cronyxin vet 50 mg/g Oral paste for horses (SE)
Cronyxin vet (DK)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
1 gram of paste contains:

flunixin	50,0 mg
(as flunixin meglumine)	83,0 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral paste
White to off-white paste

4. CLINICAL PARTICULARS

4.1 Target species

Horses

4.2 Indications for use, specifying the target species

Treatment of acute inflammatory musculoskeletal disorders in horses

4.3 Contraindications

Do not exceed the stated dose or duration of treatment.
Do not administer other NSAIDs or glucocorticosteroids concurrently or within 24 hours of each other.
Do not use in animals suffering from cardiac, hepatic or renal disease.
Do not use in animals suspected of having gastrointestinal ulceration or bleeding.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.
Do not use in dehydrated or hypovolaemic animals, except in the case of endotoxaemia or septic shock, as there is a potential risk of increased renal toxicity.
Do not use in animals suffering from chronic musculoskeletal disorders.

See also section 4.7.

4.4 Special warnings for each target species

Use of the veterinary medicinal product may lead to temporary relief due to its ameliorating effects on inflammatory signs. This may appear as effective treatment of the underlying disease.
The cause of the underlying inflammatory condition should be determined and treated with appropriate concomitant therapy.

4.5 Special precautions for use

Special precautions for use in animals
Animals should be rested and a sufficient supply of drinking water has to be ensured during the course of treatment with the veterinary medicinal product.
Use in any animal less than 6 weeks of age or in aged animals may involve additional risk.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
This product may cause serious adverse effects when ingested, particularly by children. Keep the product stored in a closed cabinet.
This product may cause hypersensitivity (allergic) reactions. Avoid skin contact with this product. Wear gloves during application. If you have known hypersensitivity reactions to non-steroidal anti-inflammatory drugs (NSAIDs), do not handle the product. In case of accidental contact with the skin wash exposed area immediately with plenty of water and soap. Hypersensitivity reactions may be serious. If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the physician this warning. Swelling of the face, lips or eyes or difficulty with breathing, are more serious symptoms and require urgent medical attention.
This product can cause eye-irritation. Avoid contact with the eyes. If the product comes into contact with the eyes, rinse immediately with plenty of water and seek medical advice.

4.6 Adverse reactions (frequency and seriousness)

As for all non-steroidal anti-inflammatory drugs, flunixin may damage the gastrointestinal mucosa and may cause renal damage particularly in hypovolemic and hypotensive conditions, e.g. during surgery.
In very rare cases allergic reactions (allergic skin reactions, anaphylaxis) may occur after administration of the veterinary medicinal product.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals 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 treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Do not use in pregnant mares since reproductive studies have not been conducted in horses.

4.8 Interaction with other medicinal products and other forms of interaction

Concurrent administration of potentially nephrotoxic drugs, particularly aminoglycosides, should be avoided. Some NSAIDs may be highly bound to plasma proteins and may compete with other highly bound drugs to produce an increase in non-bound pharmacologically active concentrations which can lead to toxic effects.
Prior or concurrent administration of steroidal or other non-steroidal anti-inflammatory drugs is not recommended since they may enhance adverse reactions.
Do not use concurrently with the inhalation anesthetic methoxyfluran because of the potential risk of nephrotoxicity.
Flunixin may reduce the effect of some anti-hypertensive medicinal products, such as diuretics, angiotensin conversion enzyme (ACE) inhibitors, and beta blockers, by inhibition of prostaglandin synthesis.

4.9 Amounts to be administered and administration route

For oral administration only.

1.1 mg flunixin per kg bodyweight once daily for a maximum of 5 days according to clinical response.

Each syringe delivers 1650 mg of flunixin, sufficient to treat 1500 kg bodyweight corresponding to a three days treatment for a 500 kg horse. The syringe is calibrated in 100 kg increments to facilitate dosing of horses of different weights.
Make sure the horse's mouth contains no feed. Insert the syringe into the horse's mouth at the interdental space. Advance the plunger as far as it will go, depositing the medication on the base of the tongue.

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

In case of overdosage, signs of toxicity such as gastrointestinal disorders and adverse reactions listed in section 4.6 can occur. In this case, the drug should be discontinued immediately and the animals treated symptomatically.

4.11 Withdrawal period(s)

Meat and offal: 15 days.
Not authorised for use in animals producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anti-inflammatory and anti-rheumatic products, non-steroids, fluxinin.
ATC vet code: QM01AG90

5.1 Pharmacodynamic properties

Flunixin meglumine is a potent non-steroidal, non-narcotic analgesic with anti-inflammatory, anti-endotoxic and anti-pyretic activities. It acts as a reversible non-selective inhibitor of the enzyme cyclo-oxygenase (both COX 1 and COX 2 forms) reducing the synthesis of eicosanoids involved in tissue inflammation, central pyresis and pain. Flunixin also inhibits the production of thromboxane, a potent platelet pro-aggregator and vasoconstrictor which is released during blood clotting.
Although flunixin has no direct effect on endotoxins, it reduces prostaglandin production and hence the effects of the prostaglandin cascade that is part of the complex processes involved in the development of endotoxic shock.

5.2 Pharmacokinetic particulars

After oral administration of the veterinary medicinal product to horses at a dose of 1.1 mg flunixin / kg body weight maximal plasma concentrations of 4.7 (± 1.1) µg/ml were reached after approximately 1.5 hours. The AUCi of flunixin was 26.2 (± 5.2) µg.hr/ml and elimination took place with a half-life of around 6 hours.
Compared to intravenous administration, a bioavailability of approximately 80 % is achieved. Flunixin strongly binds to proteins and accumulates in the inflammatory exudate, resulting in delayed elimination.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Silica, colloidal anhydrous

Propylene glycol
Titanium dioxide (E171)
Xanthan gum
Aluminium Magnesium Silicate
Sorbitol, liquid (crystallising)
Apple flavour FL02791
Purified water

6.2 Major incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 3 months.

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

White high-density polyethylene syringe barrel and dial-a-dose plunger with low-density polyethylene cap, containing 33 grams of paste. The plunger is graduated to give set doses corresponding to 100 kg bodyweight per graduation. See also section 4.9.

Marketing presentations:
Box of 1 oral syringe.
Box of 2 oral syringes.
Box of 3 oral syringes.
Box of 6 oral syringes.
Box of 12 oral syringes.

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

Bimeda Animal Health Ltd.
2,3 & 4 Airton Close,
Airton Road,
Tallaght,
Dublin 24
Ireland

8. MARKETING AUTHORISATION NUMBER(S)

<To be confirmed>

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<To be confirmed>

10. DATE OF REVISION OF THE TEXT

<To be confirmed>

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cronyxin 50 mg/g Oral paste for horses (DE, AT, BE, EE, LV, LT, ES, FR, IE, IT, NL, PL, UK)
Cronyxin vet 50 mg/g Oral paste for horses (SE)
Cronyxin vet (DK)
flunixin

2. STATEMENT OF ACTIVE SUBSTANCES

1 gram of paste contains: flunixin (as flunixin meglumine) 50 mg

3. PHARMACEUTICAL FORM

Oral paste

4. PACKAGE SIZE

1 x 33 g
2 x 33 g
3 x 33 g
6 x 33 g
12 x 33 g

5. TARGET SPECIES

Horses

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period:
Meat and offal: 15 days.
Do not use in mares producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

This product may be harmful to the user. Read the package leaflet before use.

10. EXPIRY DATE

EXP: {month/year}
Shelf life after first opening the immediate packaging: 3 months.
Once opened, use by:

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

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

Bimeda Animal Health Ltd.
2,3 & 4 Airton Close,
Airton Road,
Tallaght,
Dublin 24
Ireland

16. MARKETING AUTHORISATION NUMBER(S)

<To be confirmed>

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cronyxin 50 mg/g Oral paste for horses (DE, AT, BE, EE, LV, LT, ES, FR, IE, IT, NL, PL, UK)
Cronyxin vet 50 mg/g Oral paste for horses (SE)
Cronyxin vet (DK)
flunixin

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

1 gram of paste contains: flunixin (as flunixin meglumine) 50 mg

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 x 33 g
2 x 33 g
3 x 33 g
6 x 33 g
12 x 33 g

4. ROUTE(S) OF ADMINISTRATION

For oral administration.

5. WITHDRAWAL PERIOD(S)

Withdrawal period:
Meat and offal: 15 days
Do not use in mares producing milk for human consumption.

6. BATCH NUMBER

Lot: {number}

7. EXPIRY DATE

EXP: {month/year}
Shelf life after first opening the immediate packaging: 3 months.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Cronyxin 50 mg/g Oral paste for horses (DE, AT, BE, EE, LV, LT, ES, FR, IE, IT, NL, PL, UK)
Cronyxin vet 50 mg/g Oral paste for horses (SE)
Cronyxin vet (DK)

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:
Bimeda Animal Health Ltd.
2,3 & 4 Airton Close, Airton Road,
Tallaght, Dublin 24, Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cronyxin 50 mg/g Oral paste for horses (DE, AT, BE, EE, LV, LT, ES, FR, IE, IT, NL, PL, UK)
Cronyxin vet 50 mg/g Oral paste for horses (SE)
Cronyxin vet (DK)
flunixin

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

1 gram of paste contains:

flunixin	50,0 mg
(as flunixin meglumine)	83,0 mg

White to off-white paste

4. INDICATION(S)

Treatment of acute inflammatory musculoskeletal disorders in horses.

5. CONTRAINDICATIONS

Do not exceed the stated dose or duration of treatment.
Do not administer other NSAIDs or glucocorticosteroids concurrently or within 24 hours of each other.
Do not use in animals suffering from cardiac, hepatic or renal disease.
Do not use in animals suspected of having gastrointestinal ulceration or bleeding.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.
Do not use in dehydrated or hypovolaemic animals, except in the case of endotoxaemia or septic shock, as there is a potential risk of increased renal toxicity.
Do not use in animals suffering from chronic musculoskeletal disorders.

6. ADVERSE REACTIONS

As for all anti-inflammatory drugs from this group there is the possibility of damage to the gastrointestinal tract (ulceration); the risk of this is increased if there is dehydration or low blood pressure, e.g. during surgery, pre-existing kidney conditions. In very rare cases allergic reactions (allergic skin reactions, anaphylaxis) may occur after administration.

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

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For oral administration only.

1.1 mg flunixin per kg bodyweight once daily for a maximum of 5 days according to clinical response.

Each syringe delivers 1650 mg of flunixin, sufficient to treat 1500 kg bodyweight corresponding to a three days treatment for a 500 kg horse. The syringe is calibrated in 100 kg increments to facilitate dosing of horses of different weights.

9. ADVICE ON CORRECT ADMINISTRATION

Make sure the horse's mouth contains no feed. Insert the syringe into the horse's mouth at the interdental space (between incisor and cheek teeth). Advance the plunger as far as it will go, depositing the medication on the base of the tongue.

10. WITHDRAWAL PERIOD(S)

Meat and offal: 15 days.
Do not use in mares 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 this veterinary medicinal product after the expiry date which is stated on the label and box after EXP. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 3 months.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Use of the veterinary medicinal product may lead to temporary relief due to its ameliorating effects on inflammatory signs. This may appear as effective treatment of the underlying disease.
The cause of the underlying inflammatory condition should be determined and treated with appropriate concomitant therapy.

Special precautions use in animals:
Animals should be rested and an adequate supply of drinking water must be made available during the course of treatment.
Use in any animal less than 6 weeks of age or in aged animals may involve additional risk.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This product may cause serious adverse effects when ingested, particularly by children. Keep the product stored in a closed cabinet
This product may cause hypersensitivity (allergic) reactions. Avoid skin contact with this product. Wear gloves during application. If you have known hypersensitivity reactions to non-steroidal anti-inflammatory drugs (NSAIDs), do not handle the product. In case of accidental contact with the skin wash exposed area immediately with plenty of water and soap. Hypersensitivity reactions may be serious. If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the physician this warning. Swelling of the face, lips or eyes or difficulty with breathing, are more serious symptoms and require urgent medical attention.
This product can cause eye-irritation. Avoid contact with the eyes. If the product comes into contact with the eyes, rinse immediately with plenty of water and seek medical advice.

Pregnancy and lactation:
Do not administer to pregnant mares. Safety studies in pregnant mares have not been conducted.

Interaction with other medicinal products and other forms of interaction:
Concurrent administration of other drugs that may affect the kidneys, particularly aminoglycosides, should be avoided.
The active component of this product may be highly bound to proteins in the blood and therefore should not be given concurrently with other medicinal products that have the same property as this can result in an increase in active concentrations of either or both drugs, leading to toxic effects.
Prior or concurrent administration of steroidal or other non-steroidal anti-inflammatory drugs is not recommended since they may enhance adverse reactions.
Do not use concurrently with the inhalation anesthetic called methoxyfluran because of the potential risk of kidney damage.
Flunixin may reduce the effect of some blood pressure medications, such as diuretics, angiotensin conversion enzyme (ACE) inhibitors, and beta blockers, by inhibition of prostaglandin synthesis.

Overdose (symptoms, emergency procedures, antidotes):
In case of overdosage, poisoning symptoms such as gastrointestinal disturbances and the effects listed under adverse reactions can occur. In this case, the drug should be discontinued immediately and the animals treated symptomatically.

Incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

<To be confirmed>

15. OTHER INFORMATION

Pack sizes:

Box of 1 oral syringe.
Box of 2 oral syringes.
Box of 3 oral syringes.
Box of 6 oral syringes.
Box of 12 oral syringes.

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.