ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Container label text

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cronyxin Injection 5% w/v solution for injection
Flunixin meglumine

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

5% Solution for injection
FLUNIXIN MEGLUMINE

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml
50 ml

5. TARGET SPECIES

Cattle and horses

6. INDICATION(S)

Not applicable – prescription medicine

7. METHOD AND ROUTE(S) OF ADMINISTRATION

By slow intravenous injection.
Avoid Intra-arterial Injection

Cattle 2 ml per 45 kg bodyweight injected intravenously. Repeat as necessary at 24 hour intervals for up to 5 consecutive days. The cause of the acute inflammatory condition should be determined and treated with concomitant therapy.

Horses 1 ml per 45 kg bodyweight injected intravenously. For musculoskeletal disorders, give once daily for up to 5 consecutive days if necessary. For colic,

repeat once or twice if necessary. The cause of colic should be determined and treated with concomitant therapy.

8. WITHDRAWAL PERIOD

Withdrawal period:
Cattle: Milk 12 hours.
Meat 8 days
Horses: Not to be used in horses intended for human consumption. Treated horses may never be slaughtered for human consumption. The horse must have been declared as not intended for human consumption under national horse passport legislation.

9. SPECIAL WARNING(S), IF NECESSARY

For full directions for use, contra-indications, warnings, disposal advice etc., see package leaflet.

10. EXPIRY DATE

Expiry date:
Discard date:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C
Keep the container in the outer carton.

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

Not applicable

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 reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited
2 / 3 / 4 Airton Close,
Tallaght, Dublin 24,
Ireland

Distributed in the UK by:
Bimeda ®
Cross Vetpharm Group UK Ltd.
Unit 2, Bryn Cefni
Llangefni
Anglesey
LL77 7XA,
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 50146/4011

17. MANUFACTURER'S BATCH NUMBER

Batch No:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{NATURE/TYPE}

Not applicable

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{NATURE/TYPE}

Not applicable

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Carton label text

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cronyxin Injection 5% w/v solution for injection
Flunixin meglumine

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

5% Solution for injection
FLUNIXIN MEGLUMINE
Each ml contains Flunixin 50 mg (as Flunixin Meglumine) and 5 mg Phenol (preservative). Also contains 2.2mg Sodium Formaldehyde Sulfoxylate (Antioxidant).

3. PHARMACEUTICAL FORM

A clear, sterile, ready to use, aqueous solution for injection.

4. PACKAGE SIZE

100 ml
50 ml

5. TARGET SPECIES

Cattle and horses

6. INDICATION(S)

Not applicable – prescription medicine

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intravenous injection in cattle and horses.

8. WITHDRAWAL PERIOD

Withdrawal periods:
Cattle Milk: 12 hours.
Cattle Meat: 8 days
Horses: Not to be used in horses intended for human consumption. Treated horses may never be slaughtered for human consumption. The horse must have been declared as not intended for human consumption under national horse passport legislation.

9. SPECIAL WARNING(S), IF NECESSARY

User warnings:
Please see package leaflet for user warnings.
Following withdrawal of the first dose use the product within 28 days.
Further information and warnings – see package leaflet.

10. EXPIRY DATE

EXP: *[Embossed on the carton lid. No actual text appears on carton]*

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C
Keep container in outer carton.

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

Not applicable

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.
POM-V

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited
2 / 3 / 4 Airton Close,
Tallaght, Dublin 24,
Ireland

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United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 50146/4011

17. MANUFACTURER'S BATCH NUMBER

Lot: *[Embossed on the carton lid. No actual text appears on carton]*
MAN: *[Embossed on the carton lid. No actual text appears on carton]*

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
Cronyxin Injection, 5% w/v Solution for Injection

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

Marketing Authorisation Holder:
Bimeda Animal Health Limited
2 / 3 / 4 Airton Close,
Tallaght, Dublin 24,
Ireland

Manufacturer Responsible for Batch Release:
Labiana Life Sciences S.A.
Calle Venus 26
Can Parellada
08228 Terrassa, Barcelona
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cronyxin Injection, 5%w/v, solution for Injection

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

Each ml contains: Flunixin 50 mg (as Flunixin Meglumine) and Phenol 5 mg (Preservative). Also contains 2.2mg Sodium Formaldehyde Sulfoxylate (Antioxidant).

4. INDICATIONS

Cattle: For the control of acute inflammation associated with respiratory disease. It has also been shown to have some benefit in the treatment of experimental acute bovine pulmonary emphysema (Fog Fever). Cronyxin injection may be used as adjunctive therapy in the treatment of acute mastitis.
Horses: For the alleviation of inflammation and pain associated with musculoskeletal disorders. It is also indicated for the alleviation of visceral pain associated with colic.

5. CONTRAINDICATIONS

Do not exceed the stated dose or duration of treatment.
Do not administer other NSAIDs concurrently or within 24 hours of each other.
Avoid intra-arterial injection.

Avoid use in dehydrated, hypovolaemic or hypotensive animals as there is a potential risk of increased renal toxicity.
Use is contra-indicated in animals suffering from cardiac, hepatic or renal disease, where there is the possibility of gastro-intestinal ulceration or bleeding, or where there is evidence of a blood dyscrasia or hypersensitivity to the product.

6. ADVERSE REACTIONS

Prolonged use of NSAIDs, including flunixin, may predispose or lead to gastrointestinal irritation or in severe cases, ulceration.

7. TARGET SPECIES

Cattle and horses

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

The dose is administered by intravenous injection.

Cattle: The recommended dose is 2 ml Cronyxin Injection per 45 kg bodyweight (equivalent to 2.2 mg flunixin per kg) injected intravenously and repeated as necessary at 24 hour intervals for up to 5 consecutive days. The cause of the acute inflammatory condition should be determined and treated with concomitant therapy.

Horses: For use in equine musculoskeletal disorders the recommended dose is 1 ml Cronyxin Injection per 45 kg bodyweight (equivalent to 1.1 mg flunixin per kg) injected intravenously and repeated as necessary at 24 hour intervals for up to 5 consecutive days according to clinical response.
For use in equine colic, the recommended dose is 1 ml Cronyxin Injection per 45 kg bodyweight (equivalent to 1.1 mg flunixin per kg) injected intravenously and repeated once or twice if signs of colic recur. The cause of colic should be determined and treated with concomitant therapy.

9. ADVICE ON CORRECT ADMINISTRATION

None.

10. WITHDRAWAL PERIOD

Cattle: Milk from lactating cows should be discarded during treatment.
Milk from cows should only be taken for human consumption from 12 hours following cessation of treatment.
Cattle may not be slaughtered for human consumption during treatment.
Cattle may be slaughtered for human consumption only after 8 days from the last treatment.

Horses: Not to be used in horses intended for human consumption.
Treated horses may never be slaughtered for human consumption.
The horse must have been declared as not intended for human consumption under national horse passport legislation.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Do not store above 25 °C.
Following withdrawal of the first dose, use the product within 28 days.

When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the carton should be discarded should be worked out. This discard date should be written in the space provided.

Keep container in outer carton.

12. SPECIAL WARNING(S)

Special precautions for use in animals
Some NSAIDs may be highly bound to plasma proteins and compete with other highly bound drugs to produce an increase in non-bound pharmacologically active concentrations, which can lead to toxic effects.
Use in any animal less than 6 weeks of age or in aged animals may involve additional risk. If such use cannot be avoided animals may require a reduced dosage and careful clinical management.
It is preferable that flunixin is not administered to animals undergoing general anaesthesia until fully recovered.
NSAIDs can cause inhibition of phagocytosis and hence in the treatment of inflammatory conditions associated with bacterial infections, appropriate concurrent antimicrobial therapy should be instigated.
Concurrent administration of potentially nephrotoxic drugs should be avoided.
For animal treatment only.

Use During Pregnancy and Lactation
Do not administer to mares. Studies to demonstrate safety in pregnant mares have not been conducted.

Drug Interactions
Do not mix Cronyxin with other medicaments prior to administration.
Monitor drug compatibility closely where adjunctive therapy is required.
Due to their common mode of action, flunixin may potentiate and be potentiated by other NSAIDs which act by interfering with prostaglandin synthesis.

Special precautions to be taken by the person administering the veterinary product to animals
Avoid eye contact and direct contact with skin.

To avoid possible sensitisation reactions, avoid contact with skin. Gloves should be worn during application.
Wash hands after use.
In the case of accidental contact with eyes, rinse immediately with plenty of water and seek medical advice.
The product may cause reactions in sensitive individuals. If you have known hypersensitivity for non-steroidal anti-inflammatory products, do not handle the product. Reactions may be serious.
Avoid accidental self-injection.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2023

15. OTHER INFORMATION

Legal category: **POM-V** To be supplied only on veterinary prescription.
Package quantities: 50 ml and 100 ml bottles
Vm number: 50146/4011

Distributed by:
Bimeda ®
Cross Vetpharm Group UK Ltd.
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Approved 11 October 2023