LABEL TEXT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprieve 50 mg/ml Solution for Injection for Cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Carprofen 50 mg/ml
Ethanol (as preservative) 100 mg/ml
Sodium Formaldehyde Sulphoxylate (as antioxidant) 2.0 mg/ml

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

50ml

5. TARGET SPECIES

Cattle

6. INDICATION(S)

Reduction of pyrexia in acute cases of infectious respiratory disease in cattle, in combination with appropriate anti-infective therapy.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Single subcutaneous or intravenous injection at a dosage of 1.4 mg carprofen per kilogram (1ml/35kg) bodyweight in combination with antibiotic therapy, as appropriate.

For further information see Package Insert.

8. WITHDRAWAL PERIOD

Milk: Zero hours.

Meat and offal: 21 days.

9. SPECIAL WARNING(S), IF NECESSARY

See package leaflet for user safety warnings.

10. EXPIRY DATE

D.O.M.:
Exp.:

Shelf-life after first opening the container: 28 days.

Once broached, use by:_____

11. SPECIAL STORAGE CONDITIONS

Protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

FOR ANIMAL TREATMENT ONLY

POM-V

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

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing Authorisation Holder:
(EU)
Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

(UK)
Norbrook Laboratories Limited
Station Works
Newry
Co. Down
BT35 6JP

16. MARKETING AUTHORISATION NUMBER(S)

VM 02000/4295

17. MANUFACTURER'S BATCH NUMBER

B.N.:

CARTON TEXT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprieve 50 mg/ml Solution for Injection for Cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Carprofen 50 mg/ml.
Ethanol (as preservative) 100 mg/ml
Sodium Formaldehyde Sulphoxylate (as antioxidant) 2.0 mg/ml

3. PHARMACEUTICAL FORM

Solution for Injection.

4. PACKAGE SIZE

50ml

5. TARGET SPECIES

Cattle

6. INDICATION(S)

Reduction of pyrexia in acute cases of infectious respiratory disease in cattle, in combination with appropriate anti-infective therapy.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Single subcutaneous or intravenous injection at a dosage of 1.4 mg carprofen per kilogram (1ml/35kg) bodyweight in combination with antibiotic therapy, as appropriate.

8. WITHDRAWAL PERIOD

Milk: Zero hours.

Meat and offal: 21 days.

9. SPECIAL WARNING(S), IF NECESSARY

CONTRAINDICATIONS, WARNINGS, ETC:
Do not use in animals suffering from cardiac, hepatic or renal impairment, where there is a possibility of gastrointestinal ulceration or bleeding, or where there is evidence of a blood dyscrasia or hypersensitivity to the product.
The safety of the veterinary medicinal product has not been established during pregnancy. Use only accordingly to the benefit/risk assessment by the responsible veterinarian.
Do not exceed the stated dose or the duration of treatment.
Do not administer other NSAIDs concurrently or within 24 hours of each other.

Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of increased renal toxicity. Concurrent administration of potentially nephrotoxic drugs should be avoided.

In common with other NSAIDs, carprofen should not be administered simultaneously with another product of the NSAID or glucocorticoid class. Animals should be carefully monitored if carprofen is administered simultaneously with an anticoagulant. NSAIDs are highly bound to plasma proteins and may compete with other highly bound drugs, which can lead to toxic effects.
Studies in cattle have shown that a transient local reaction may form at the site of subcutaneous injection.
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.
There is no specific antidote for carprofen overdosage but general supportive therapy, as applied to clinical overdosage with NSAIDs should be applied.

OPERATOR WARNINGS:
Avoid skin contact with the product. Wash off any splashes immediately. Take care to avoid accidental self-injection.

Carprofen, in common with other NSAIDs, has been shown to exhibit photosensitising potential in laboratory studies.

10. EXPIRY DATE

D.O.M.:
EXP:

Shelf-life after first opening the container: 28 days.

Once broached, use by:_____

11. SPECIAL STORAGE CONDITIONS

Protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

FOR ANIMAL TREATMENT ONLY

POM-V

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

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing Authorisation Holder:
(EU)
Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

(UK)
Norbrook Laboratories Limited
Station Works
Newry
Co. Down
BT35 6JP

16. MARKETING AUTHORISATION NUMBER(S)

VM 02000/4295

17. MANUFACTURER'S BATCH NUMBER

B.N.

INSERT TEXT

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

Marketing Authorisation Holder:
(EU) Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

(UK) Norbrook Laboratories Limited
Station Works
Newry
Co. Down
BT35 6JP

Manufacturer Responsible for Batch Release:
Norbrook Manufacturing Ltd
Rossmore Industrial Estate
Monaghan
Ireland

Norbrook Laboratories Limited
Station Works
Newry
Co. Down, BT35 6JP

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprieve 50 mg/ml Solution for Injection for Cattle

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

Carprieve 50 mg/ml Solution for Injection for Cattle is a solution for injection containing 50 mg/ml carprofen, 100 mg/ml ethanol (as preservative) and 2.0 mg/ml sodium formaldehyde sulphoxylate (as antioxidant).

4. INDICATION(S)

Reduction of pyrexia in acute cases of infectious respiratory disease in cattle, in combination with appropriate anti-infective therapy.

5. CONTRAINDICATIONS

Do not use in animals suffering from cardiac, hepatic or renal impairment, where there is a possibility of gastrointestinal ulceration or bleeding, or where there is evidence of a blood dyscrasia or hypersensitivity to the product.

6. ADVERSE REACTIONS

Studies in cattle have shown that a transient local reaction may form at the site of subcutaneous injection, however this should disappear within 24 hours after the injection.

If you notice any serious side effects or any other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle

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

Single subcutaneous or intravenous injection at a dosage of 1.4 mg carprofen per kilogram (1ml/35kg) bodyweight in combination with antibiotic therapy, as appropriate.

9. ADVICE ON CORRECT ADMINISTRATION

See the above section.

10. WITHDRAWAL PERIOD

Milk: Zero hours.

Meat and offal: 21 days.

11. SPECIAL STORAGE PRECAUTIONS

Protect from light.
Shelf-life after first opening the container: 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 container should be discarded should be worked out. This discard date should be written in the space provided on the label.

Do not use after the expiry date which is stated on the vial and carton label after EXP:

Keep out of the reach and sight of children.

12. SPECIAL WARNINGS

Do not exceed the stated dose or the duration of treatment.
Do not administer other NSAIDs concurrently or within 24 hours of each other.

Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of increased renal toxicity. Concurrent administration of potentially nephrotoxic drugs should be avoided.

In common with other NSAIDs, carprofen should not be administered simultaneously with another product of the NSAID or glucocorticoid class. Animals should be carefully monitored if carprofen is administered simultaneously with an anticoagulant. NSAIDs are highly bound to plasma proteins and may compete with other highly bound drugs, which can lead to toxic effects.
There is no specific antidote for carprofen overdosage but general supportive therapy, as applied to clinical overdosage with NSAIDs should be applied.

The safety of the veterinary medicinal product has not been established during pregnancy. Use only accordingly to the benefit/risk assessment by the responsible veterinarian.
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.

USER WARNINGS

Carprofen, in common with other NSAIDs, has been shown to exhibit photosensitising potential in laboratory studies.

Avoid skin contact with the product. Wash off any splashes immediately. Take care to 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 2022

15. OTHER INFORMATION

MARKETING AUTHORISATION NUMBER

VM 02000/4295

DISTRIBUTED BY:
Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
Co. Down
BT35 6QQ
Northern Ireland

Carprieve Injection for Cattle is available in 1 x 50ml, 5 x 50ml, 6 x 50ml, 10 x 50ml and 12 x 50ml multidose amber glass (Type I) vials, sealed with 20mm bromobutyl bungs and 20mm aluminium seals.
Not all pack sizes may be marketed.

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Approved 28 October 2022