

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{CARTON}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprofen Norbrook 50 mg/ml Solution for Injection

2. STATEMENT OF ACTIVE SUBSTANCES

Carprofen 50 mg/ml

3. PACKAGE SIZE

1 x 50 ml
5 x 50 ml
6 x 50 ml
12 x 50 ml

4. TARGET SPECIES

Cattle.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

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

7. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: 21 days.
Milk: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

Keep the bottle in the outer carton in order to protect from light.
Store in an upright position.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited

14. MARKETING AUTHORISATION NUMBERS

UK(NI) Vm 02000/3012
UK(GB) Vm 02000/5020

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{Label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprofen Norbrook 50 mg/ml Solution for Injection

2. STATEMENT OF ACTIVE SUBSTANCES

Carprofen 50 mg/ml

3. TARGET SPECIES

Cattle

4. ROUTES OF ADMINISTRATION

s.c, i.v.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: 21 days
Milk: Zero hours

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.
Use by.....

7. SPECIAL STORAGE PRECAUTIONS

Keep the bottle in the outer carton in order to protect from light.
Store in an upright position.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Carprofen Norbrook 50 mg/ml Solution for Injection for Cattle

2. Composition

Each ml contains:

Active substance:

Carprofen 50 mg

Excipients:

Ethanol anhydrous 0.1 ml
Sodium formaldehyde sulfoxylate 2.0 mg

A clear, colourless to pale yellow solution.

3. Target species

Cattle.

4. Indications for use

The veterinary medicinal product is indicated as an adjunct to antimicrobial therapy to reduce clinical signs in acute infectious respiratory disease and acute mastitis in cattle.

5. Contraindications

Do not use in animals suffering from cardiac, hepatic, or renal impairment.
Do not use in animals suffering from gastro-intestinal ulceration or bleeding.
Do not use where there is evidence of blood dyscrasia.
Do not use in cases of hypersensitivity to the active substance, or to any of the excipients.

6. Special warnings

Special precautions for safe use in the target species:

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

Do not exceed the stated dose or the duration of treatment.

Do not administer other non-steroidal anti-inflammatory drugs (NSAIDs) concurrently or within 24 hours of each other.

As NSAID therapy can be accompanied by gastro-intestinal or renal impairment, adjunctive fluid therapy should be considered especially in the case of acute mastitis treatment.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Carprofen, in common with other NSAIDs, has been shown to exhibit photosensitising potential in laboratory studies. Avoid skin contact with the veterinary medicinal product. Should this occur, wash the affected areas immediately.

Administer the veterinary medicinal product with caution to avoid self-injection. In case of accidental self-injection, seek medical advice and show the package leaflet or the label to the physician.

Pregnancy:

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

Interaction with other medicinal products and other forms of interaction:

In common with other NSAIDs, carprofen should not be administered simultaneously with another veterinary medicinal product of the NSAID or glucocorticoid class.

NSAIDs are highly bound to plasma proteins and may compete with other highly bound drugs, such that concomitant administration may result in toxic effects.

However, during clinical studies in cattle four different antibiotic classes were used (macrolides, tetracyclines, cephalosporins and potentiated penicillins) were used in combination with a carprofen containing veterinary medicinal product without known interactions.

Overdose:

In clinical studies, no adverse signs were reported after intravenous and subcutaneous administration of up to 5 times the recommended dose.

There is no specific antidote for carprofen overdosage but general supportive therapy, as applied to clinical overdosage with NSAIDs, should be applied.

Major incompatibilities:

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

7. Adverse events

Cattle.

Very common (>1 animal / 10 animals treated):	Injection site reaction ¹
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¹Transient, lasting no more than 24 hours.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Subcutaneous or intravenous use.

Single subcutaneous (**s.c.**) or intravenous (**i.v.**) injection at a dosage of 1.4 mg carprofen/kg bodyweight (corresponding to 1ml of the veterinary medicinal product/35 kg bodyweight) in combination with antibiotic therapy, as appropriate.

9. Advice on correct administration

When treating groups of animals, use a draw-off needle or a multi-dose syringe to avoid excessive broaching of the stopper. The maximum number of broachings should be limited to 3.

10. Withdrawal periods

Meat and offal: 21 days.

Milk: Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Keep the bottle in the outer carton in order to protect from light.

Store in an upright position.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 28 days.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with

any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

UK(NI) Vm 02000/3012
UK(GB) Vm 02000/5020

50 ml multidose amber type I glass vials with bromobutyl rubber stoppers and aluminium seals in a cardboard box.

Pack sizes:

Cardboard box containing 1 vial of 50 ml
Cardboard box containing 5 vials of 50 ml
Cardboard box containing 6 vials of 50 ml
Cardboard box containing 12 vials of 50 ml

For multi-vial pack sizes, each vial will be packed in an individual carton within an outer cardboard box.

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder <and contact details to report suspected adverse reactions>:

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

Manufacturer responsible for batch release:
Norbrook Laboratories Limited, 105 Armagh Road,
Newry, Co. Down, BT35 6PU, Northern Ireland

Norbrook Manufacturing Limited, Rossmore Industrial
Estate, Monaghan, Ireland

<Local representatives <and contact details to report suspected adverse reactions>:>

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

17. Other information

POM-V

Gavin Hall
Approved: 12 February 2026