

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprofen Norbrook 50 mg/ml Solution for Injection for Cattle [AT, BE, CZ, DE, EL, ES, FI, FR, HR, IE, IT, NL, NO, PT, RO, SK, SI, UK-NI]  
Carprofen Norbrook [DK, NO]

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

### Active substance:

Carprofen                      50 mg

### Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Ethanol anhydrous	0.1 ml
Sodium Formaldehyde Sulphoxylate	2.0 mg
Macrogol 600	
Macrogol 4000	
Arginine	
Sodium Hydroxide	
Water for Injections	

A clear colourless to pale yellow solution.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Cattle.

### 3.2 Indications for use for each target species

This 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.

### 3.3 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.

### 3.4 Special warnings

None.

### 3.5 Special precautions for use

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 accidental self-injection. In case of accidental self-injection, seek medical advice and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

### **3.6 Adverse events**

Cattle.

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

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

### **3.7 Use during pregnancy, lactation or lay**

The safety of the veterinary medicinal product has not been established during pregnancy.

Pregnancy:

Use only according to the benefit/risk assessment by the responsible veterinarian.

### **3.8 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 (macrolides, tetracyclines, cephalosporins and potentiated penicillins) were used in combination with a carprofen containing veterinary medicinal product without known interactions.

### **3.9 Administration routes and dosage**

Subcutaneous or intravenous use.

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

### **3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)**

In clinical studies, no adverse events 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.

### **3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance**

Not applicable.

### **3.12 Withdrawal periods**

Meat and offal: 21 days.

Milk: Zero days.

## **4. PHARMACOLOGICAL INFORMATION**

### **4.1 ATCvet code:**

QM01AE91

### **4.2 Pharmacodynamics**

Carprofen is a member of the 2-arylpropionic acid group of non-steroidal anti-inflammatory drugs and possesses anti-inflammatory, analgesic, and antipyretic activity.

Carprofen, like most other NSAIDs is an inhibitor of the enzyme cyclo-oxygenase of the arachidonic acid cascade. However, the inhibition of prostaglandin synthesis by carprofen is slight in relation to its anti-inflammatory and analgesic potency. The precise mode of action is unclear.

Studies have shown that carprofen has potent antipyretic activity and significantly reduces the inflammatory response in lung tissue in cases of acute, pyretic infectious respiratory disease in cattle. Studies in cattle with experimentally induced acute mastitis have shown that carprofen administered intravenously has potent antipyretic activity and improves heart rate and rumen function.

### **4.3 Pharmacokinetics**

Absorption: Following a single subcutaneous dose of 1.4 mg carprofen/kg the maximum plasma concentration ( $C_{max}$ ) of 15.4 µg/ml was reached after ( $T_{max}$ ) 7 – 19 hours.

**Distribution:** The highest carprofen concentrations are found in bile and plasma and more than 98% of carprofen is bound to plasma proteins. Carprofen was well distributed in the tissues with the highest concentrations found in kidney and liver followed by fat and muscle.

**Metabolism:** Carprofen (parent compound) is the main component in all tissues. Carprofen (parent compound) is slowly metabolised primarily by ring hydroxylation, hydroxylation at the  $\alpha$ -carbon and by conjugation of the carboxylic acid group with glucuronic acid. The 8-hydroxylated metabolite and unmetabolized carprofen predominate in the faeces. Bile samples are comprised of conjugated carprofen.

**Elimination:** Carprofen has a plasma elimination half-life of 70 hours. Carprofen is primarily excreted in the faeces, indicating that the biliary secretion plays an important role.

## **5. PHARMACEUTICAL PARTICULARS**

### **5.1 Major incompatibilities**

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

### **5.2 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale: 2 years

Shelf life after first opening the immediate packaging: 28 days

### **5.3 Special precautions for storage**

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

Store in an upright position.

### **5.4 Nature and composition of immediate packaging**

50 ml multidose amber type I glass vial with bromobutyl rubber stopper 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.

### **5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products**

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 national collection systems applicable to the veterinary medicinal product concerned.

## **6. NAME OF THE MARKETING AUTHORISATION HOLDER**

**7. MARKETING AUTHORISATION NUMBER(S)**

**8. DATE OF FIRST AUTHORISATION**

Date of first authorisation: <{DD/MM/YYYY}> <{DD month YYYY}>.

**9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS**

{MM/YYYY}

**10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the [Union Product Database](https://medicines.health.europa.eu/veterinary) (<https://medicines.health.europa.eu/veterinary>).

**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.

<b>11. THE WORDS “FOR ANIMAL TREATMENT ONLY”</b>
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For animal treatment only.

<b>12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”</b>
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Keep out of the sight and reach of children.

<b>13. NAME OF THE MARKETING AUTHORISATION HOLDER</b>
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<b>14. MARKETING AUTHORISATION NUMBERS</b>
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<b>15. BATCH NUMBER</b>
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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 days.

**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**

**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 <sup>1</sup>
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<sup>1</sup>Transient, 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:

### **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**

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. Date on which the package leaflet was last revised**

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the [Union Product Database](https://medicines.health.europa.eu/veterinary) (<https://medicines.health.europa.eu/veterinary>).

**16. Contact details**

Marketing authorisation holder <and manufacturer responsible for batch release> <and contact details to report suspected adverse reactions>:

Manufacturer responsible for batch release:

<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>**