

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box with 1 vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Curacef Duo 50 mg/ml + 150 mg/ml Suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Ceftiofur (as hydrochloride)	50.0	mg/ml
Ketoprofen	150.0	mg/ml

3. PACKAGE SIZE

1 x 50 ml
1 x 100 ml
1 x 250 ml

4. TARGET SPECIES

Cattle.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Meat and offal: 8 days.
Milk: zero hours.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use within 28 days.

Once broached, use by...

9. SPECIAL STORAGE PRECAUTIONS

Do not freeze.
Keep the glass vial in the outer carton in order to protect from light.

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

VIRBAC

14. MARKETING AUTHORISATION NUMBERS

Vm 05653/3016

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Glass or plastic vial of 50 or 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Curacef Duo

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

50.0	mg/ml
150.0	mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Glass or plastic vials of 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Curacef Duo 50 mg/ml + 150 mg/ml Suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Ceftiofur (as hydrochloride)	50.0 mg/ml
Ketoprofen	150.0 mg/ml

3. TARGET SPECIES

Cattle.

4. ROUTES OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Meat and offal: 8 days.
Milk: zero hours.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use
by...

7. SPECIAL STORAGE PRECAUTIONS

Do not freeze.
For the glass vial only: Keep the glass vial in the outer carton in order to protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

VIRBAC

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Curacef Duo 50 mg/ml + 150 mg/ml Suspension for injection for cattle

2. Composition

Each ml contains:

Active substances:

Ceftiofur (as hydrochloride)	50.0	mg
Ketoprofen	150.0	mg

Off - white to pinkish suspension for injection.

3. Target species

Cattle.

4. Indications for use

For the treatment of bovine respiratory disease (BRD) caused by *Mannheimia haemolytica* and *Pasteurella multocida* susceptible to ceftiofur and the reduction of associated clinical signs of inflammation or pyrexia.

5. Contraindications

Do not use in cases of hypersensitivity to ceftiofur and other β -lactam antibiotics.

Do not use in cases of hypersensitivity to ketoprofen.

Do not use in cases of known resistance to other cephalosporins or beta-lactam antibiotics.

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

Do not use in animals suffering from cardiac, hepatic or renal disease, where there is the possibility of gastro-intestinal ulceration or bleeding, where there is evidence of a blood dyscrasia.

6. Special warnings

Special precautions for safe use in the target species:

The veterinary medicinal product selects for resistant strains such as bacteria carrying extended spectrum betalactamases (ESBL) and may constitute a risk to human health if these strains disseminate to humans e.g. via food. For this reason, the veterinary medicinal product should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly (refers to very acute cases when treatment must be initiated without bacteriological diagnosis) to first line treatment.

When inflammation or pyrexia have subsided, the veterinarian should switch to a ceftiofur only-containing product in order to cover 3 to 5 days of continuous

antibiotic treatment. Treating for an appropriate length of time is important to limit development of resistance.

Official, national and regional antimicrobial policies should be taken into account when the veterinary medicinal product is used. Increased use, including use of the product deviating from the instructions given in the SPC, may increase the prevalence of such resistance. Whenever possible, the veterinary medicinal product should only be used based on susceptibility testing.

The veterinary medicinal product is intended for treatment of individual animals. Do not use for disease prevention or as a part of herd health programmes. Treatment of groups of animals should be strictly restricted to ongoing disease outbreaks according to the approved conditions of use.

The concomitant use of diuretics or coagulant should be based on a benefit/risk assessment of the responsible veterinarian.

Avoid intra-arterial and intravenous injection.

Avoid use in any dehydrated, hypovolaemic or hypotensive animals as there is a potential risk of increased renal toxicity.

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

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross reactions to cephalosporins and vice versa. Ketoprofen may also cause hypersensitivity. Allergic reactions to these substances may occasionally be serious. Do not handle this veterinary medicinal product if you know you are sensitised to active substances or to any of the ingredients, or if you have been advised not to work with such preparations.

Wash hands after use.

Avoid contact with eyes and skin. In case of contact, wash immediately with water.

If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning.

Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

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

Pregnancy and lactation:

Laboratory studies with ceftiofur or ketoprofen have shown no evidence of teratogenesis effects, abortion or influence on reproduction. The safety of the veterinary medicinal product has not been established during pregnancy.

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

Interaction with other medicinal products and other forms of interaction:

Some NSAIDs may be highly bound to plasma proteins and compete with other highly bound drugs which can lead to toxic effects.

Do not use in combination with other NSAIDs or with corticosteroids, diuretics, nephrotoxic drugs or anticoagulants.

The bactericidal properties of beta-lactams are neutralised by simultaneous use of bacteriostatic antibiotics (macrolides, sulphonamides and tetracyclines).

Overdose:

No signs of systemic toxicity of the veterinary medicinal product have been observed at doses up to 5 times the recommended daily dose for 15 consecutive days.

Special restrictions for use and special conditions for use:

Do not use in poultry (including eggs) due to risk of spread of antimicrobial resistance to humans.

Major incompatibilities:

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

7. Adverse events

Cattle:

Common (1 to 10 animals / 100 animals treated)
Injection site inflammation (e.g. Injection site oedema (injection site swelling)) ¹ .
Very rare (<1 animal / 10,000 animals treated, including isolated reports)
Hypersensitivity reactions (e.g. Anaphylaxis (severe allergic reaction), allergic skin reaction) ²
Ruminant stomach disorder ³
Renal disorder ³
Skin discolouration and/or Muscle discolouration.

¹Mild and without pain in most cases.

¹In case of the occurrence of allergic reaction the treatment should be withdrawn.

²Unrelated to dose.

³In common with all NSAIDs due to their action of inhibition of prostaglandin synthesis.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal 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: {national system details}

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

Intramuscular use.

1 mg ceftiofur /kg /day and 3 mg ketoprofen /kg /day by intramuscular injection, i.e. 1 ml/50 kg at each injection. The veterinary medicinal product should only be used when the disease is associated with clinical signs of inflammation or pyrexia. The veterinary medicinal product may be administered for 1 to 5 consecutive days depending upon the clinical response on a case by case basis. As the duration for the antibiotic treatment should not be less than 3 to 5 days, when inflammation and pyrexia have subsided, the veterinarian should switch to a ceftiofur only-containing

product in order to cover 3 to 5 days of continuous antibiotic treatment. Only few animals are expected to require a fourth or fifth injection with the combined product.

9. Advice on correct administration

Shake the bottle vigorously for 20 seconds before use to ensure an homogeneous suspension.

Resuspension could be longer after storage at low temperatures.

To ensure correct dosage body weight should be determined as accurately as possible to avoid underdosing.

The user should use the most appropriate vial size according to the number of animals to treat. 50 ml and 100 ml vials should not be pierced more than 10 times and the 250 ml not more than 18 times. The use of an aspirating needle may be recommended to avoid excessive broaching of the stopper

Subsequent intramuscular injections must be given at different sites.

Not more than 16 ml should be administered per injection site.

Use preferably a 14 gauge needle.

10. Withdrawal periods

Meat and offal: 8 days.

Milk: zero hours.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not freeze.

Keep the glass vial in the outer carton in order to protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label or carton after Exp.

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

Vm 05653/3016

1 x 50 ml, 1 x 100 ml and 1 x 250 ml (glass vials or polypropylene vials).

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 manufacturer responsible for batch release and contact details to report suspected adverse reactions:

VIRBAC
1^{ère} avenue 2065m LID
06516 Carros
FRANCE

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

Approved 18 May 2024
Gavin Hall