PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Cardboard box of 50 ml, 100 ml & 250 ml vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cevaxel-RTU 50 mg/ml, Suspension for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 vial contains:
Ceftiofur (as hydrochloride) 50 mg/ml

3. PACKAGE SIZE

50 ml
100 ml
250 ml

4. TARGET SPECIES

Cattle and pigs.

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Cattle: Subcutaneous use.
Pigs: Intramuscular use.

7. WITHDRAWAL PERIODS

Meat & offal:
Pigs: 5 days.
Cattle: 8 days
Milk: zero hours.

8. EXPIRY DATE

EXP:
Once broached, use within 28 days by: _____/___/____

9. SPECIAL STORAGE PRECAUTIONS

Keep the 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

Penicillins and cephalosporins may occasionally cause severe allergic reactions.

See package leaflet for user warnings.

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

Ceva Animal Health Ltd

14. MARKETING AUTHORISATION NUMBER

Vm 15052/4051

15. BATCH NUMBER

Lot

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

(100 ml and 250 ml labels)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cevaxel-RTU 50 mg/ml, suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

1 vial contains:
Ceftiofur (as hydrochloride) 50 mg/ml

3. TARGET SPECIES

Cattle and pigs.

4. ROUTES OF ADMINISTRATION

Cattle: Subcutaneous use.
Pigs: Intramuscular use.

5. WITHDRAWAL PERIODS

Meat & offal:
Pigs: 5 days.
Cattle: 8 days
Milk: zero hours

6. EXPIRY DATE

EXP:
Once broached, use within 28 days by: _____/___/____

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd

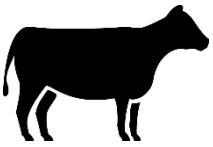
9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS (50 ml label)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cevaxel-RTU



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Ceftiofur (as hydrochloride) 50 mg/ml

3. BATCH NUMBER

Lot

4. EXPIRY DATE

EXP:
Once broached, use within 28 days by: ___/___/___

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Cevaxel-RTU 50 mg/ml, suspension for injection for cattle and pigs
Ceftiofur

2. Composition

Each ml contains:
Ceftiofur (as hydrochloride) 50 mg

3. Target species

Cattle and pigs.

4. Indications for use

Infections associated with bacteria sensitive to ceftiofur.

In Cattle:
For the treatment of bacterial respiratory disease associated with *Pasteurella multocida*, *Mannheimia haemolytica* and *Histophilus somi*.
For the treatment of acute interdigital necrobacillosis (panaritium, foot rot), associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus* (*Porphyromonas asaccharolytica*).
For treatment of the bacterial component of acute post-partum (puerperal) metritis within 10 days after calving associated with *Escherichia coli*, *Trueperella pyogenes* and *Fusobacterium necrophorum*: this indication is restricted to cases where treatment with another antimicrobial has failed

In Pigs:
For the treatment of bacterial respiratory disease associated with *Pasteurella multocida*, *Actinobacillus pleuropneumoniae* and *Streptococcus suis*.

5. Contraindications

Do not administer to an animal previously found to be hypersensitive to ceftiofur and other β-lactam antibiotics.
Do not inject intravenously.
Do not use where resistance to other cephalosporins or beta-lactam antibiotics has occured.
Do not use in poultry (including eggs) due to risk of spread of antimicrobial resistance to

humans.

6. Special warnings

Special precautions for safe use in the target species:

Use of Cevaxel-RTU may constitute a risk to public health due to spread of antimicrobial resistance.
Cevaxel-RTU should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly to first line treatment. Official, national and regional antimicrobial policies should be taken into account when the product is used. Increased use, including use of the product deviating from the instructions given, may increase the prevalence of resistance. Whenever

Cevaxel-RTU is intended for treatment of individual animals. Do not use for disease prevention or as a part of heard health programmes. Treatment of groups of animals should be strictly restricted to ongoing disease outbreaks according to the approved conditions of use.

Do not use as prophylaxis in case of retained placenta.

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. Allergic reactions to these substances may occasionally be serious.

- Do not handle this product if you know you are sensitised or if you have been advised not to work with such preparations.
- Handle this product with great care to avoid exposure. Wash hands after use.
- 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.

Pregnancy and lactation:
Studies in laboratory animals have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects. The safety of the product has not been established in sows or cows during pregnancy and lactation.
Use only according to a benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
The bactericidal properties of cephalosporins are antagonized by simultaneous use of bacteriostatic antibiotics (macrolides, sulfonamides and tetracyclines).

Overdose:
The low toxicity of ceftiofur has been demonstrated in pigs using ceftiofur sodium at doses in excess of 8 times the recommended daily dose of ceftiofur intramuscularly

administered for 15 consecutive days.
In cattle, no signs of systemic toxicity have been observed following substantial parenteral overdosages.

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

7. Adverse even

Cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction[1], Allergic skin reaction[1], Anaphylaxis[1]
Rare (1 to 10 animals / 10,000 animals treated):	Injection site reaction[2] (e.g. inflammation, oedema, thickening[3], discoloration[4])

[1]In case of the occurrence of allergic reaction the treatment should be withdrawn.
[2]Clinical resolution is reached in most animals by 10 days after injection although slight tissue discoloration may persist for 28 days or more.
[3]Of connective tissue
[4]Of the subcutaneous tissue and/or fascial surface of the muscle

Pigs

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction[1], Allergic skin reaction[1], Anaphylaxis[1]
Undetermined frequency (cannot be estimated from the available data)	Injection site reaction (e.g. discoloration) [2]

[1]In case of the occurrence of allergic reaction the treatment should be withdrawn.
[2] Of the fascia or fat, mild, observed in some animals for up to 20 days after injection.

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 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

Cattle: Subcutaneous use
- Respiratory disease: 1 mg ceftiofur (as hydrochloride)/kg /day for 3 to 5 days, i.e. 1 ml/50 kg at each injection.
- Acute interdigital necrobacillosis: 1 mg ceftiofur (as hydrochloride)/kg /day for 3 days, i.e. 1 ml/50 kg at each injection.
- Acute post-partum metritis within 10 days after calving: 1 mg ceftiofur (as hydrochloride)/kg /day for 5 consecutive days, i.e. 1 ml/50 kg at each injection.

In case of acute post-partum metritis, additional supportive therapy might be required in some cases.

Pigs: Intramuscular use
3 mg ceftiofur (as hydrochloride)/kg /day for 3 days, i.e. 1 ml/16 kg at each injection.

9. Advice on correct administration

Shake the bottle well before use to bring the product back into suspension.
To ensure a correct dosage, body weight should be determined as accurately as possible in order to avoid under-dosing. Subsequent injections must be given at different sites.
As the vial cannot be broached more than 50 times, the user should choose the more appropriate vial size.

10. Withdrawal periods

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

Pigs:
Meat and offal: 5 days.

11. Special storage precautions

Keep out of the sight and reach of children.
Keep the vial in the outer carton in order to protect from light.
Shelf life after first opening the immediate packaging: 28 days.
Do not use after the expiry date which is stated on the carton after EXP. The expiry

date refers to the last day of that month.

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 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 15052/4051
Cardboard box containing one 100 ml vial
Cardboard box containing one 250 ml vial
Cardboard box containing one 50 ml vial

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:
Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom
Tel: 00800 35 22 11 51
Email for the reporting of adverse events: pharmacovigilance@ceva.com

Manufacturer responsible for batch release:
Ceva Santé Animale, 10 av. de La Ballastière, 33500 Libourne, France

17. Other information

POM-V

Veterinary Medicinal product subject to prescription
For animal treatment only

Approved 05 March 2025
Gavin Hall