PARTICULARS TO APPEAR ON THE OUTER PACKAGE
PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Cardboard boxes of 50, 100 & 250 ml
Vials of 100 & 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

50 ml
100 ml
250 ml

5. TARGET SPECIES

Cattle and pigs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle: Subcutaneous use.
Pigs: Intramuscular use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

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

9. SPECIAL WARNING(S), IF NECESSARY

Penicillins and cephalosporins may occasionally cause severe allergic reactions. See package leaflet for user warnings.

10. EXPIRY DATE

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

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

[Not required on the immediate label]
Disposal: Read package leaflet

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

For animal treatment only.
To be supplied only on veterinary prescription.

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

[Not required on the immediate label]
Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 15052/4159

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial of 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cevaxel-RTU 50 mg/ml, suspension for injection for cattle and pigs
Ceftiofur (as hydrochloride)

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Ceftiofur (as hydrochloride) 50 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

50 ml

4. ROUTE(S) OF ADMINISTRATION

Cattle: SC
Pigs: IM

5. WITHDRAWAL PERIOD

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

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET FOR

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

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

Marketing authorisation holder:
Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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

Each ml contains:
Ceftiofur (as hydrochloride) 50 mg

4. INDICATION(S)

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*, *Arcanobacterium 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 □ -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. ADVERSE REACTIONS

Hypersensitivity reactions (e.g. skin reactions, anaphylaxia) have been reported in very rare cases. In case of the occurrence of hypersensitivity reaction the treatment should be withdrawn.
In pigs, mild reactions at the injection site, such as discoloration of the fascia or fat, have been observed in some animals for up to 20 days after injection.
In cattle, mild inflammatory reactions at the injection site, such as tissue oedema, thickening of connective tissue and discoloration of the subcutaneous tissue and/or fascial surface of the muscle may be observed in rare cases. Clinical resolution is reached in most animals by 10 days after injection although slight tissue discoloration may persist for 28 days or more.
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

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

7. TARGET SPECIES

Cattle and pigs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 PERIOD

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 vial: 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 WARNING(S)

Special precautions for use in animals

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 possible, Cevaxel RTU should only be used based on susceptibility testing.

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.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

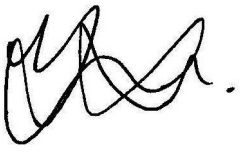
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2022

15. OTHER INFORMATION

Pack sizes:
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.



Approved: 28 September 2022