PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Polystyrene box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ceftiosan, 50 mg/ml, suspension for injection for pigs and cattle

Ceftiofur (as ceftiofur hydrochloride)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains: Ceftiofur 50.0 mg
(as ceftiofur hydrochloride)

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

15x 50 ml
12x 100 ml
6x 250 ml

5. TARGET SPECIES

Pigs weighing up to 125 kg.
Cattle.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Pigs: intramuscular injection
Cattle: subcutaneous injection

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:
Pigs:
Meat and offal: 8 days.
Cattle:

Meat and offal: 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: MM/YY
Shelf life after first opening the immediate packaging: 28 days

11. SPECIAL STORAGE CONDITIONS

Do not refrigerate or freeze. Protect from frost.

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

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

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"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Alfasan Nederland BV
Kuipersweg 9
3449 JA Woerden
The Netherlands
Tel.: ++31348416945
Fax: ++31348483676

16. MARKETING AUTHORISATION NUMBER

Vm 36408/4000

17. MANUFACTURER'S BATCH NUMBER

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ceftiosan, 50 mg/ml, suspension for injection for pigs and cattle

Ceftiofur (as ceftiofur hydrochloride)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains: Ceftiofur 50.0 mg
(as ceftiofur hydrochloride)

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

50 ml
100 ml
250 ml

5. TARGET SPECIES

Pigs weighing up to 125 kg.
Cattle.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Pigs: intramuscular injection
Cattle: subcutaneous injection

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:
Pigs:
Meat and offal: 8 days.
Cattle:
Meat and offal: 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: MM/YY
Once broached, use by ….
Shelf life after first opening the immediate packaging: 28 days

11. SPECIAL STORAGE CONDITIONS

Do not refrigerate or freeze. Protect from frost.

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

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

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"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Alfasan Nederland BV
Kuipersweg 9
3449 JA Woerden
The Netherlands
Tel. : ++31348416945
Fax: ++31348483676

16. MARKETING AUTHORISATION NUMBER

Vm 36408/4000

17. MANUFACTURER'S BATCH NUMBER

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vials type II

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ceftiosan, 50 mg/ml, suspension for injection for pigs and cattle

Ceftiofur (as ceftiofur hydrochloride)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains: Ceftiofur 50.0 mg
(as ceftiofur hydrochloride)

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

50 ml
100 ml
250 ml

5. TARGET SPECIES

Pigs weighing up to 125 kg.
Cattle.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Pigs: intramuscular injection
Cattle: subcutaneous injection

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:
Pigs:
Meat and offal: 8 days.
Cattle:
Meat and offal: 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: MM/YY
Once broached, use by ….
Shelf life after first opening the immediate packaging: 28 days

11. SPECIAL STORAGE CONDITIONS

Do not refrigerate or freeze. Protect from frost.

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

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

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"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Alfasan Nederland BV
Kuipersweg 9
3449 JA Woerden
The Netherlands
Tel. : ++31348416945
Fax: ++31348483676

16. MARKETING AUTHORISATION NUMBER

Vm 36408/4000

17. MANUFACTURER'S BATCH NUMBER

PACKAGE LEAFLET

Ceftiosan, 50 mg/ml, suspension for injection for pigs and cattle

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

Alfasan Nederland BV
Kuipersweg 9
3449 JA Woerden
The Netherlands
Tel. : ++31348416945
Fax: ++31348483676

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ceftiosan, 50 mg/ml, suspension for injection for pigs and cattle

Ceftiofur (as ceftiofur hydrochloride)

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

Each ml of white to off white coloured suspension contains:
Ceftiofur 50.0 mg
(as Ceftiofur hydrochloride)

4. INDICATION(S)

Infections associated with bacteria sensitive to ceftiofur:

In pigs:
-Treatment of bacterial respiratory disease associated with *Pasteurella multocida*, *Actinobacillus pleuropneumoniae* and *Streptococcus suis*.
This product is not to be used in pigs with a bodyweight more than 125 kg.

In cattle:
-Treatment of bacterial respiratory disease associated with *Mannheimia haemolytica*, *Pasteurella multocida* and *Histophilus somni* (previously *Haemophilus somnus*).
-Treatment of acute interdigital necrobacillosis (panaritium, foul in the foot), associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus* (*Porphyromonas asaccharolytica*).
-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*, sensitive to ceftiofur. The indication is restricted to cases where treatment with another antimicrobial has failed.

5. CONTRAINDICATIONS

Do not inject intravenously.
Do not administer to an animal previously found to be hypersensitive to ceftiofur and other β-lactam antibiotics or to any of the excipients.
Do not use in poultry (including eggs) due to risk of spread of antimicrobial resistance to humans.

6. ADVERSE REACTIONS

Hypersensitivity reactions unrelated to dose can occur. Allergic reactions (e.g. skin reactions, anaphylaxia) may occasionally occur. In case of the occurrence of allergic 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 and discoloration of the subcutaneous tissue and/or fascial surface of the muscle may be observed. Clinical resolution is reached in most animals by 10 days after injection although slight tissue discoloration may persist for 28 days or more.

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

7. TARGET SPECIES

Pigs weighing up to 125 kg.
Cattle.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Pigs:
Bacterial respiratory disease: 3 mg ceftiofur /kg bw/day for 3 days via intramuscular route, i.e. 1 ml/16 kg bw at each injection.

The maximum injection volume must not exceed 4 ml per injection site. Each injection must be given at separate sites, with no overlap of subsequent injections. This product is not to be used in pigs with a bodyweight more than 125 kg.

Cattle:
Bacterial respiratory disease: 1 mg ceftiofur /kg bw/day for 3 to 5 days by subcutaneous injection, i.e. 1 ml/50 kg bw at each injection.
Acute interdigital necrobacillosis: 1 mg/kg bw/day for 3 days by subcutaneous injection, i.e. 1 ml/50 kg bw at each injection.
Acute post-partum metritis within 10 days after calving: 1 mg/kg bw/day for 5 consecutive days by subcutaneous injection, i.e. 1 ml/50 kg bw at each injection.
In case of acute post-partum metritis, additional supportive therapy might be required in some cases.

Each injection must be given at separate sites, with no overlap of subsequent injections.

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.
As the vial cannot be broached more than 40 times, the user should choose the most appropriate vial size.

9. ADVICE ON CORRECT ADMINISTRATION

Shake before use to bring product back into suspension.

10. WITHDRAWAL PERIOD

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

11. SPECIAL STORAGE PRECAUTIONS

Do not refrigerate or freeze. Protect from frost.

Shelf-life after first broaching of the container: 28 days.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after EXP.

Keep out of the sight and reach of children.

12. SPECIAL WARNING(S)

Special warnings for each target species
Do not use in case of known resistance to the active substance.
Cross resistance to other lactam antibiotics can be present. Do not use in cases such cross-resistance is known.

Special precautions for use
Shake the bottle well before use to bring the product back into suspension.

Special precautions for use in animals
In case of the occurrence of allergic reaction the treatment should be withdrawn.

Ceftiosan 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.

Do not use as prophylaxis in case of retained placenta.

Use of Ceftiosan may constitute a risk to public health due to spread of antimicrobial resistance.
Ceftiosan 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. 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, Ceftiosan should only be used based on susceptibility testing.

User warnings
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, taking all recommended precautions.
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.
Wash hands after use.

Use during pregnancy, lactation or lay
Laboratory studies have not produced any evidence of a teratogenic, foetotoxic or maternotoxic effects. The safety of the veterinary medicinal product has not been established in the target species during pregnancy and lactation.
Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

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

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

Overdose (symptoms, emergency procedures, antidotes), if necessary
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 administered intramuscularly . for 15 consecutive days.
In cattle, no signs of systemic toxicity have been observed following substantial parenteral overdosages.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Carton box containing one glass vial, type II 50 ml, sealed with a bromobutyl rubber stopper and aluminium overseal.
Polystyrene box containing 15 glass vials, type II 50 ml, sealed with a bromobutyl rubber stopper and aluminium overseal.
Carton box containing one glass vial, type II 100 ml, sealed with a bromobutyl rubber stopper and aluminium overseal.
Polystyrene box containing 12 glass vials, type II 100 ml, sealed with a bromobutyl rubber stopper and aluminium overseal.
Carton box containing one glass vial, type II 250 ml, sealed with a bromobutyl rubber stopper and aluminium overseal.
Polystyrene box containing 6 glass vials, type II 250 ml, sealed with bromobutyl rubber stopper and aluminium overseal.

Not all pack sizes may be marketed.

Approved: 03 March 2017