B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Diacef 50 mg/ml suspension for injection for pigs and cattle

2. Composition

Each ml contains:
Active substances:
Ceftiofur .....50 mg
(equivalent to 53.48 mg ceftiofur hydrochloride)

Homogeneous and lump-free white-cream colour suspension

3. Target species

Pigs and cattle.

4. Indications for use

Infections associated with bacteria susceptible to ceftiofur:

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

In cattle:
For the treatment of bacterial respiratory disease associated with *Mannheimia haemolytica* (previously *Pasteurella haemolytica*), *Pasteurella multocida* and *Histophilus somni* (previously *Haemophilus somnus*).
For the treatment of acute interdigital necrobacillosis (panaritium, foot rot), associated with *Fusobacterium necrophorum* and *Porphyromonas asaccharolytica* (previously *Bacteroides melaninogenicus*).
For the treatment of the bacterial component of acute post-partum (puerperal) metritis within 10 days after calving associated with *Escherichia coli*, *Trueperella pyogenes* (previously *Arcanobacterium pyogenes*) and *Fusobacterium necrophorum*, susceptible to ceftiofur, where treatment with another antimicrobial has failed.

5. Contraindications

Do not use in cases of hypersensitivity to the active substance, to other beta-lactam antibiotics or to any of the excipients. Do not inject intravenously.
Do not use in poultry (including eggs) due to risk of spread of antimicrobial resistance to humans.

6. Special warnings

Special warnings:

None.

Special precautions for safe use in the target species:

This veterinary medicinal product selects for resistant strains such as bacteria carrying extended-spectrum beta-lactamases (ESBL) and may constitute a risk to human health if these strains disseminate to humans e.g. via food.
Do not use as prophylaxis in case of retained placenta.
This veterinary medicinal product 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.

Use of this veterinary product may constitute a risk to public health due to spread of antimicrobial resistance.

This veterinary medicinal product should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly to first line treatment (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, this veterinary medicinal product should only be used based on susceptibility testing.

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..
People with known hypersensitivity to cephalosporins or penicillins should avoid contact with the veterinary medicinal product.. Handle this veterinary medicinal product with great care to avoid exposure taking all recommended precautions.
In case of accidental self-injection or if you develop symptoms following exposure such as a skin rash, seek medical advice immediately and show the package leaflet or the label to the physician. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.Wash hands after use.

Pregnancy :

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

Interaction with other medicinal products and other forms of interaction:

The bactericidal properties of beta-lactams are neutralised by simultaneous use of bacteriostatic antibiotics (macrolides, sulfonamides and tetracyclines).
Aminoglycosides may have a potentiating effect on cephalosporins.

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.

Special restrictions for use and special conditions for use:

Major incompatibilities:

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

7. Adverse events

Pigs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Hypersensitivity reaction[1,2], allergic reaction[2], allergic skin reaction[2], anaphylaxis[2] Injection site reaction[3], injection site fascia or fat discoloration[4]

[1] Unrelated to dose can occur.
[2] In this case the treatment should be withdrawn.
[3] Mild
[4] For up to 20 days after injection

Cattle:

Very common (>1 animal / 10 animals treated):
Application site inflammation chronic [1,2]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):.
Hypersensitivity reaction[3,4], allergic reaction[4], allergic skin reaction[3], anaphylaxis[4] Oedema injection site[5], swelling injection site[5]

[1] Mild to moderate
[2] Until 18 days post injection
[3] Unrelated to dose can occur.
[4] In this case the treatment should be withdrawn.
[5] After subcutaneous 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 <or its local representative > 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

Pigs:
Intramuscular use.
3 mg ceftiofur/kg bw/day for 3 consecutive days, equivalent to 1 ml veterinary medicinal product/16 kg bw at each injection.
The maximum volume at injection site should be 5.4 ml.

Cattle:
Subcutaneous use.
Respiratory disease: 1 mg ceftiofur /kg bw/day for 3 to 5 consecutive days, equivalent to 1 ml veterinary medicinal product/50 kg bw at each injection.
Acute interdigital necrobacillosis: 1 mg ceftiofur/kg bw/day for 3 consecutive days, equivalent to 1 ml veterinary medicinal product/50 kg bw at each injection.
Acute post-partum metritis within 10 days after calving: 1 mg ceftiofur/kg bw/day for 5 consecutive days, equivalent to 1 ml veterinary medicinal product/50 kg bw at each injection.
The maximum volume at injection site should be 6.8 ml.
In case of acute post-partum metritis, additional supportive therapy might be required in some cases.

Subsequent injections must be given at different sites.
Shake the vial well before use to bring the veterinary medicinal product back into suspension.
The stopper should not be punctured more than 50 times.

9. Advice on correct administration

Shake the vial well before use to bring the veterinary medicinal product back into suspension.

10. Withdrawal periods

Pigs:
- Meat and offal: 5 days.

Cattle:
- Meat and offal: 6 days
- Milk: zero 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
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
Shelflife 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 number and pack sizes

Pack sizes:

Cardboard box with 1 vial of 100 ml
Cardboard box with 1 vial of 250 ml

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).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse events:
SUPER'S DIANA, S.L.
Ctra. C-17, km 17
ES-08150 PARETS DE VALLÈS (Barcelona)
Tel: +34 93 843 75 36