

1.B.2 LABELLING AND PACKAGE LEAFLET

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box of 100 ml and 250 ml.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

Ceftiofur (as ceftiofur hydrochloride)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One ml contains:

Ceftiofur (as ceftiofur hydrochloride) 50 mg

Excipients, q.s. 1 ml

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

100 ml

250 ml

5. TARGET SPECIES

Pigs and cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Pigs: Intramuscular use

Cattle: Subcutaneous injection

Shake well before use

Read the package leaflet before use

8. WITHDRAWAL PERIOD

Pigs:

Meat and offal: 5 days.

Cattle:

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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP: MM/YYYY

Shelf life after first opening the immediate packaging: 28 days

11. SPECIAL STORAGE CONDITIONS

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 products should be disposed of in accordance with 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 REACH AND SIGHT OF CHILDREN”

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder:

Laboratorios e Industrias IVEN, S.A.

Luís I, 56

28031 MADRID (Spain)

Manufacturer:

Laboratorios Maymó, S.A.

Vía Augusta, 302

08017, Barcelona (Spain)

16. MARKETING AUTHORISATION NUMBER(S)

XXXXXXXX

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle of 100 ml and 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

Ceftiofur (as ceftiofur hydrochloride)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One ml contains:

Ceftiofur (as ceftiofur hydrochloride) 50 mg

Excipients, q.s. 1 ml

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

100 ml

250 ml

5. TARGET SPECIES

Pigs and cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Pigs: Intramuscular use

Cattle: Subcutaneous injection

Shake well before use

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Pigs:

Meat and offal: 5 days.

Cattle:

- Meat and offal: 8 days

- Milk: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP: MM/YYYY

Shelf life after first opening the immediate packaging: 28 days.

Once opened, use by...

11. SPECIAL STORAGE CONDITIONS

No special storage precautions are required.

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

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 REACH AND SIGHT OF CHILDREN”

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder:

Laboratorios e Industrias IVEN, S.A.

Luís I, 56

28031 MADRID (Spain)

Manufacturer:

Laboratorios Maymó, S.A.

Vía Augusta, 302

08017, Barcelona (Spain)

16. MARKETING AUTHORISATION NUMBER(S)

XXXXXXXXXX

17. MANUFACTURER'S BATCH NUMBER

Lot:

PACKAGE LEAFLET

Ceftionil, 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, IF DIFFERENT

Marketing authorisation holder:

Laboratorios e Industrias IVEN, S.A.
Luís I, 56
28031 MADRID (Spain)

Manufacturer:

Laboratorios Maymó, S.A.
Vía Augusta, 302
08017, Barcelona (Spain)

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ceftionil, 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)

Composition

One ml contains:

Ceftiofur (as ceftiofur hydrochloride) 50 mg
Excipients, q.s. 1 ml

4. INDICATION(S)

Infections associated with bacteria sensitive 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*, *Pasteurella multocida* and *Haemophilus sommus*.
- 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*, sensitive to ceftiofur.

The indication is restricted to cases where treatment with another antimicrobial has failed.

5. CONTRAINDICATIONS

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 inject intravenously.

The product should not be used in the case of known resistance to the ceftiofur or to other beta-lactam antibiotics.

Do not use in poultry (including eggs) due to risk of spread 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 minimal residual lesions in the intermuscular connective tissue consisting of round clear areas, have been observed in some animals for up to 20-22 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 32 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 and cattle.

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

Pigs:

- 3 mg ceftiofur /kg bw/day for 3 days via intramuscular route, i.e. 1 ml/16 kg bw at each injection.

Cattle:

- 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: 1mg/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.

Subsequent injections must be given at different sites. A maximum volume of 6 ml may be administered in each injection site.

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 more appropriate vial size.

9. ADVICE ON CORRECT ADMINISTRATION

Overdose (symptoms, emergency procedures, antidotes)

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.

10. WITHDRAWAL PERIOD

Pigs:

- Meat and offal: 5 days.

Cattle:

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

11. SPECIAL STORAGE PRECAUTIONS

Do not use after the expiry date stated on the label.

Shelf-life after first opening the container: 28 days.

Keep out of the reach and sight of children.

12. SPECIAL WARNINGS

Special warnings for each target species

None known.

Special precautions for use in animals

Shake the bottle well for 30 seconds before use to bring the veterinary medicinal product back into suspension.

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

Use of CEFTIONIL may constitute a risk to public health due to spread of antimicrobial resistance.

CEFTIONIL 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 in the SPC, may increase the prevalence of such resistance. Whenever possible, CEFTIONIL 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.

Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.

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.

Handle this product with great care to avoid exposure. Wash hands after use.

Use during pregnancy, lactation or lay

Studies in laboratory species have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects. Safety has not been established in the target species during pregnancy or lactation. Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

Incompatibilities

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

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 products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

MM/YYYY

15. OTHER INFORMATION


Package size

100 ml, 250 ml


Not all pack sizes may be marketed.

MOCK-UPS OF OUTER AND IMMEDIATE PACKAGING

DRAFT MOCK-UP OF OUTER LABELLING:

<p>Method and route of administration Pigs: Intramuscular use Cattle: Subcutaneous injection Shake well before use</p> <p>Shelf life after first opening the immediate packaging: 28 days.</p> <p>Special precautions for the disposal of unused product or waste materials Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.</p> <p>Keep out of the reach and sight of children.</p> <p>Read the package leaflet before use.</p>	<p>FOR ANIMAL TREATMENT ONLY</p> <p style="text-align: center;">Ceftionil</p> <p style="text-align: center;">50 mg/ml</p> <p style="text-align: center;">Suspension for injection for pigs and cattle</p> <p style="text-align: center;">Ceftiofur (as ceftiofur hydrochloride)</p> <p style="text-align: center;">100 ml / 250 ml</p> <p style="text-align: center;">TO BE SUPPLIED ONLY ON VETERINARY PRESCRIPTION</p>	<p>Composition One ml contains: Ceftiofur (as ceftiofur hydrochloride) 50 mg Excipients, q.s. 1 ml</p> <p>Target species Pigs and Cattle</p> <p>Withdrawal period Pigs: Meat and offal: 5 days Cattle: Meat and offal: 8 days Milk: zero days.</p> <p>Marketing Authorisation N.:</p> <p>Manufacturer: Laboratorios Maymó, S.A. Via Augusta, 302 08017, Barcelona (Spain)</p> <p>Marketing authorisation holder: Laboratorios e Industrias IVEN, S.A. Luis I, 56. 28031 MADRID (Spain)</p> 	<p>FOR ANIMAL TREATMENT ONLY</p> <p style="text-align: center;">Ceftionil</p> <p style="text-align: center;">50 mg/ml</p> <p style="text-align: center;">Suspension for injection for pigs and cattle</p> <p style="text-align: center;">Ceftiofur (as ceftiofur hydrochloride)</p> <p style="text-align: center;">100 ml / 250 ml</p> <p style="text-align: center;">TO BE SUPPLIED ONLY ON VETERINARY PRESCRIPTION</p>
			<p>Lot: EXP: MM/YYYY</p>

DRAFT MOCK-UP OF INNER LABEL:

Ceftionil		
Composition One ml contains: Ceftiofur (as ceftiofur hydrochloride) 50 mg Excipients, q.s. 1 ml	50 mg/ml Suspension for injection for pigs and cattle	Withdrawal period Pigs: Meat and offal: 5 days Cattle: Meat and offal: 8 days Milk: zero days
Pigs: Intramuscular use Cattle: Subcutaneous injection Shake well before use Read the package leaflet before use. Keep out of the reach and sight of children.	Ceftiofur (as ceftiofur hydrochloride) 100 ml / 250 ml For animal treatment only	To be supplied only on veterinary prescription.
Marketing authorisation holder: Laboratorios e Industrias IVEN, S.A. Luis I, 56. 28031 MADRID (Spain)	Manufacturer: Laboratorios Maymó, S.A. Vía Augusta, 302 08017, Barcelona (Spain)	Marketing Authorisation N.: Shelf-life after first opening the container: 28 days. Once opened, use by ...
		Lot: EXP: MM/YYYY

DRAFT MOCK-UP OF PACKAGE LEAFLET

CEFTIONIL

50 mg/ml, suspension for injection, for pigs and cattle
Ceftiofur hydrochloride

Composition

One ml contains:

Ceftiofur (as hydrochloride) 50 mg
Excipients, q.s. 1 ml

Indications

Infections associated with bacteria sensitive to ceftiofur:

Pigs:

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

Cattle:

- For the treatment of bacterial respiratory disease associated with *Mannheimia haemolytica*, *Pasteurella multocida* and *Haemophilus sommus*.
- 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*, sensitive to ceftiofur.

The indication is restricted to cases where treatment with another antimicrobial has failed.

Contraindications

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 inject intravenously.

The product should not be used in the case of known resistance to the ceftiofur or to other beta-lactam antibiotics.

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

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 minimal residual lesions in the intermuscular connective tissue consisting of round clear areas of 2 mm of diameter or smaller, have been observed in some animals for up to 20-22 days after injection.

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

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 32 days or more.

Target species

Pigs and cattle

Dosage for each species, route and method of administration

Pigs:

- 3 mg ceftiofur /kg bw/day for 3 days via intramuscular route, i.e. 1 ml/16 kg bw at each injection.

Cattle:

- 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.

Subsequent injections must be given at different sites. A maximum volume of 6 ml may be administered in each injection site.

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 more appropriate vial size.

Overdose (symptoms, emergency procedures, antidotes)

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.

Withdrawal period

Pigs: Meat and offal: 5 days

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

Special Storage Precautions

Do not use after the expiry date stated on the label.

Shelf-life after first opening the container: 28 days.

Keep out of the reach and sight of children.

Special warnings for each target species

None known

Special precautions for use in animals

Shake the bottle well for 30 seconds before use to bring the veterinary medicinal product back into suspension.

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

Use of CEFTIONIL may constitute a risk to public health due to spread of antimicrobial resistance.

CEFTIONIL 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 in the SPC, may increase the prevalence of such resistance. Whenever possible, CEFTIONIL should only be used based on susceptibility testing.

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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.

Handle this product with great care to avoid exposure. Wash hands after use.

Use during pregnancy, lactation or lay

Studies in laboratory species have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects. Safety has not been established in the target species during

pregnancy or lactation. Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

Incompatibilities

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

Special precautions for the disposal of unused product or waste materials

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

Manufacturer:

Laboratorios Maymó, S.A. Vía Augusta, 302. 08017, Barcelona (Spain)

Marketing authorisation holder:

Laboratorios e Industrias IVEN, S.A. Luís I, 56. 28031 MADRID (Spain)

Date on which the package leaflet was last approved: MM/YYYY

Other information

Package size

100 ml, 250 ml

Not all pack sizes may be marketed.