

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Ceftiofur 50 mg (as Ceftiofur Hydrochloride)

Excipients:

Qualitative composition of excipients and other constituents
Aluminium monostearate
Sorbitan oleate
Triglycerides, medium-chain.

A white or yellowish oily suspension

3. CLINICAL INFORMATION

3.1 Target species

Pigs and cattle.

3.2 Indications for use for each target species

Infections associated with bacteria sensitive to ceftiofur:

Pigs:

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

Cattle:

- For the treatment of bacterial respiratory disease associated with *Histophilus somni*, *Mannheimia haemolytica* and *Pasteurella multocida*.

- For the treatment of acute interdigital necrobacillosis (panaritium, foot rot) associated with *Bacteroides melaninogenicus* (*Porphyromonas asaccharolytica*) and *Fusobacterium necrophorum*.

- For the treatment of the bacterial component of acute post-partum (puerperal) metritis within 10 days after calving associated with *Arcanobacterium pyogenes*, *Escherichia coli* and *Fusobacterium necrophorum* (restricted to cases where treatment with another antimicrobial has failed).

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to other β -lactam antibiotics.

Do not inject intravenously.

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

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

In case of the occurrence of allergic reaction the treatment should be withdrawn.

Ceftiofur 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. Ceftiofur 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.

Use of the product should be in accordance with official, national and regional antimicrobial policies. Increased use, including use of the product deviating from the instructions given in the SPC, may increase the prevalence of such resistance. Whenever possible, ceftiofur should only be based on susceptibility testing.

Ceftiofur should only be used in 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 (see section 3.2 Indications for use, specifying the target species).

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.

People with known hypersensitivity to penicillins or cephalosporins should avoid contact with the product.

In the case of accidental self-injection or following exposure, if you develop symptoms 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle:

Very rare (<1 animals / 10 000 animals treated):	Injection site reaction ¹ (e.g. oedema, discoloration ²) Hypersensitivity reaction ³ , allergic reaction (e.g. allergic skin reaction, anaphylaxis)
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¹ Mild inflammatory reactions. Clinical resolution is reached in most animals by 10 days after injection although slight tissue discoloration may persist for 28 days or more.

² Of the subcutaneous tissue and/or fascial surface of the muscle.

³ Unrelated to dose.

Pigs:

Very rare (<1 animals / 10 000 animals treated):	Injection site reaction ¹ (e.g. discoloration ²) Hypersensitivity reaction ³ , allergic reaction (e.g. allergic skin reaction, anaphylaxis)
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¹ Mild reactions, up to 20 days after injection.

² Of the fascia or fat.

³ Unrelated to dose.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy.

Pregnancy:

Laboratory studies in species have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects. Use only according to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

The bactericidal properties of β -lactams are neutralised by simultaneous use of bacteriostatic antibiotics (macrolides, sulphonamides and tetracyclines).

3.9 Administration routes and dosage

Pigs: intramuscular use.

Cattle: subcutaneous use.

Pigs:

3 mg ceftiofur/kg bw/day for 3 days by intramuscular injection, i.e. 1 ml of the product /16 kg bw/day.

Cattle:

Treatment of respiratory disease: 1 mg ceftiofur/kg bw/day for 3 to 5 days by subcutaneous injection, i.e. 1 ml of the product /50 kg bw/day.

Treatment of acute interdigital necrobacillosis: 1 mg ceftiofur/kg bw/day for 3 days by subcutaneous injection, i.e. 1 ml of the product /50 kg bw/day.

Acute post-partum metritis within 10 days after calving: 1 mg ceftiofur/kg bw/day for 5 consecutive days by subcutaneous injection, i.e. 1 ml of the product /50 kg bw/day.

Subsequent injections must be given at different sites.

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

To ensure a correct dosage, body weight should be determined as accurately as possible.

Shake well before use.

3.10 Symptoms of overdose (and where applicable, emergency procedures and 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 overdoses.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

3.12 Withdrawal periods

Pigs:

Meat and offal: 5 days.

Cattle:

Meat and offal: 8 days.

Milk: zero days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code : QJ01DD90.

4.2 Pharmacodynamics

Ceftiofur is a third generation cephalosporin, which is active against Gram-positive and Gram-negative bacteria. Like all beta-lactam antibiotics, ceftiofur inhibits bacterial cell wall synthesis, thereby exerting bactericidal properties.

Cell wall synthesis is dependent on enzymes that are called penicillin-binding proteins (PBPs). Bacteria may develop resistance to cephalosporins by 1) having penicillin binding proteins insensitive to an otherwise effective β -lactam; 2) altering cell membrane permeability to β -lactams; 3) producing β -lactamases that cleave the β -lactam ring of the antibiotic, or 4) active efflux.

Some β -lactamases, documented in Gram-negative enteric organisms, may lead to varying degrees of cross resistance between cephalosporins, as well as with penicillins, ampicillins and β -lactam inhibitor combinations.

Ceftiofur is active against the following microorganisms which are involved in respiratory diseases in pigs: *Pasteurella multocida*, *Actinobacillus pleuropneumoniae* and *Streptococcus suis*. *Bordetella bronchiseptica* is intrinsically non-susceptible to ceftiofur.

It is also active against bacteria involved in respiratory disease in cattle: *Pasteurella multocida*, *Mannheimia haemolytica*, *Histophilus somni*; bacteria involved in acute bovine foot rot (interdigital necrobacillosis): *Fusobacterium necrophorum*, *Bacteroides melaninogenicus* (*Porphyromonas asaccharolytica*); and bacteria associated with acute post-partum (puerperal) metritis in cattle: *Escherichia coli*, *Arcanobacterium pyogenes* and *Fusobacterium necrophorum*.

The following Minimum Inhibitory Concentrations (MIC) have been determined for ceftiofur in European isolates of target bacteria:

PIGS		
Organism (number of isolates)	MIC range ($\mu\text{g/mL}$)	MIC ₉₀ ($\mu\text{g/mL}$)
<i>A. pleuropneumoniae</i> (28)	$\leq 0.03^*$	≤ 0.03
<i>Pasteurella multocida</i> (37)	≤ 0.03 -0.13	≤ 0.03
<i>Streptococcus suis</i> (495)	≤ 0.03 -0.25	≤ 0.03

CATTLE

Organism (number of isolates)	MIC range (µg/mL)	MIC ₉₀ (µg/mL)
<i>Mannheimia</i> spp. (87)	≤ 0.03*	≤ 0.03
<i>P. multocida</i> (42)	≤ 0.03-0.12	≤ 0.03
<i>H. somni</i> (24)	≤ 0.03*	≤ 0.03
<i>Arcanobacterium pyogenens</i> (123)	≤ 0.03-0.5	0.25
<i>Escherichia coli</i> (188)	0.13-> 32.0	0.5
<i>Fusobacterium necrophorum</i> (67) (from cases of foot rot)	≤ 0.06-0.13	ND
<i>Fusobacterium necrophorum</i> (2) (from cases of acute metritis)	≤ 0.03-0.06	ND

* No range; all isolates yielded the same value. ND: not determined.

The following breakpoints are recommended by NCCLS for bovine and porcine respiratory pathogens:

Zone Diameter (mm)	MIC (µg/mL)	Interpretation
≥ 21	≤ 2.0	(S) Susceptible
18-20	4.0	(I) Intermediate
≤ 7	≥ 8.0	(R) Resistant

No breakpoints have been determined to date for the pathogens associated with foot rot or acute post-partum metritis in cows.

4.3 Pharmacokinetics

After administration, ceftiofur is quickly metabolised to desfuroylceftiofur, the principal active metabolite.

Desfuroylceftiofur has an equivalent anti-microbial activity to ceftiofur against the bacteria involved in respiratory disease in animals. It is reversibly bound to plasma proteins and as a result, the metabolite concentrates at sites of infection. It remains active in the presence of necrotic tissue and debris.

Pigs

A single intramuscular dose of the product at 3 mg ceftiofur/kg body weight resulted in mean C_{max} of approximately 9 microgram/mL after about 1 hour. The terminal elimination half-life (t_{1/2}) of desfuroylceftiofur was about 23 hours. No accumulation of desfuroylceftiofur has been observed after a dose of 3 mg ceftiofur/kg bw/day administered daily over 3 days.

Elimination occurs mainly via the urine (more than 70%); 12-15 % is eliminated via faeces.

Ceftiofur is completely bioavailable following intramuscular administration.

Cattle

A single subcutaneous dose of the product at 1 mg ceftiofur/kg resulted in mean C_{max} of approximately 2 microgram/mL after about 2.5 hours. After administration of the product, the terminal elimination half-life (t_{1/2}) of desfuroylceftiofur in cattle is approximately 18 hours.

In other studies in healthy cows, a mean C_{max} of approximately 2.25 microgram/mL was reached in the endometrium about 5 hours after a single administration of ceftiofur. Maximum mean concentrations reached in caruncles and lochia of healthy cows were about 1 microgram/mL.

No accumulation of desfuroylceftiofur has been observed after a daily treatment of ceftiofur over 5 days. Elimination occurs mainly via the urine (more than 55%). 31% is eliminated in the faeces.

Ceftiofur is completely bioavailable following subcutaneous administration.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf-life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Glass and PET bottles

Do not store above 25 °C.
Do not refrigerate or freeze.

PET bottles

Keep the PET bottles in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

Type II glass bottles of 50, 100 and 250 ml.
Polyethylene terephthalate (PET) bottles of 50, 100 and 250 ml.
The bottles are closed with a Type I bromobutyl closure and aluminium cap
The 250 ml glass bottle has a colourless plastic package as a protective measure in order to avoid glass bottle breaking when it is being used.

Pack sizes:

Cardboard box with 1 glass bottle of 50 ml.
Cardboard box with 1 glass bottle of 100 ml.
Cardboard box with 1 glass bottle of 250 ml.
Cardboard box with 10 glass bottles of 100 ml.
Cardboard box with 12 glass bottles of 100 ml.

Cardboard box with 1 PET bottle of 50 ml.
Cardboard box with 1 PET bottle of 100 ml.
Cardboard box with 1 PET bottle of 250 ml.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: DD/MM/YYYY

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

DD/MM/YYYY

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

ANNEX III
LABELLING AND PACKAGE LEAFLET

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX with 1 glass/PET bottle of 50 ml
CARDBOARD BOX with 1 glass/PET bottle of 100 ml
CARDBOARD BOX with 1 glass/PET bottle of 250 ml
CARDBOARD BOX with 10 glass bottle of 100 ml
CARDBOARD BOX with 12 glass bottle of 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EFICUR 50 mg/ml suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Ceftiofur 50 mg (as Ceftiofur Hydrochloride)

3. PACKAGE SIZE

1 x 50 ml
1 x 100 ml
1 x 250 ml
10 x 100 ml
12 x 100 ml

4. TARGET SPECIES

Pigs and cattle.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Pigs: Intramuscular use
Cattle: subcutaneous use

7. WITHDRAWAL PERIODS

Pigs:
Meat and offal: 5 days.

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

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.
Once broached, used by.....

9. SPECIAL STORAGE PRECAUTIONS

Glass and PET bottles

Do not store above 25 °C.

Do not refrigerate or freeze.

PET bottles

Keep the PET bottles 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.

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

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Glass/PET bottle of 100 ml
Glass/PET bottle of 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EFICUR 50 mg/ml suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Ceftiofur 50 mg (as Ceftiofur Hydrochloride)

3. TARGET SPECIES

Pigs and cattle

4. ROUTES OF ADMINISTRATION

Pigs: Intramuscular use.
Cattle: Subcutaneous use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Pigs:
Meat and offal: 5 days.

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

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 28 days.
Once broached, used by.....

7. SPECIAL STORAGE PRECAUTIONS

Glass and PET bottles
Do not store above 25 °C.
Do not refrigerate or freeze.

PET bottles
Keep the PET bottles in the outer carton in order to protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

9. BATCH NUMBER

Lot {number}

10. PACKAGE SIZE

100 ml

250 ml

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Glass/PET bottle of 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EFICUR

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each ml contains:

Ceftiofur 50 mg (as Ceftiofur Hydrochloride)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.

Once broached, used by.....

5. MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

50 ml

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each ml contains:

Active substance:

Ceftiofur 50 mg (as Ceftiofur Hydrochloride)

A white or yellowish oily suspension

3. Target species

Pigs and cattle.

4. Indications for use

Infections associated with bacteria sensitive to ceftiofur:

Pigs:

Treatment of bacterial respiratory disease associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida* and *Streptococcus suis*.

Cattle:

For the treatment of bacterial respiratory disease associated with *Histophilus somni*, *Mannheimia haemolytica* and *Pasteurella multocida*.

For the treatment of acute interdigital necrobacillosis (panaritium, foot rot) associated with *Bacteroides melanogenicus* (*Porphyromonas asaccharolytica*) and *Fusobacterium necrophorum*.

For the treatment of the bacterial component of acute post-partum (puerperal) metritis within 10 days after calving associated with *Arcanobacterium pyogenes*, *Escherichia coli* and *Fusobacterium necrophorum* (restricted to cases where treatment with another antimicrobial has failed).

5. Contraindications

Do not use in cases of hypersensitivity to the active substance and to other β -lactam antibiotics.

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 precautions for safe use in the target species:

In case of the occurrence of allergic reaction the treatment should be withdrawn. Ceftiofur selects for resistant strains such as bacteria carrying extended spectrum betalactamases (ESBL) and may constitute a risk to human health if these strains disseminate to humans e.g. via food.

Ceftiofur should only be used in individual animals. Ceftiofur should not be used for 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 (see Section 4 Indications).

Use of veterinary medicinal product may constitute a risk to public health due to the spread of antimicrobial resistance

Ceftiofur should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly to first line treatment. Used of the product should be in accordance with official, national and regional antimicrobial policies.

Increased use, including use of the product deviating from the instructions given, may increase the prevalence of resistance. Whenever possible, ceftiofur should only be used based on susceptibility testing.

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.

People with known hypersensitivity to penicillins or cephalosporins should avoid contact with the product.

In the case of accidental self-injection or following exposure, if you develop symptoms 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.

Pregnancy:

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

Interaction with other medicinal products and other forms of interaction:

The bactericidal properties of β -lactams are neutralised by simultaneous use of bacteriostatic antibiotics (macrolides, sulphonamides 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 overdoses.

Major incompatibilities:

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

7. Adverse events

Cattle:

<p>Very rare (<1 animals / 10 000 animals treated):</p>	<p>Injection site reaction¹ (e.g. oedema (swelling), discoloration²) Hypersensitivity reaction³, allergic reaction (e.g. allergic skin reaction, anaphylaxis (severe allergic reaction))</p>
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¹ Mild inflammatory reactions. Clinical resolution is reached in most animals by 10 days after injection although slight tissue discoloration may persist for 28 days or more.

² Of the subcutaneous tissue and/or fascial surface of the muscle.

³ Unrelated to dose.

Pigs:

Very rare (<1 animals / 10 000 animals treated):	Injection site reaction ¹ (e.g. discoloration ²) Hypersensitivity reaction ³ , allergic reaction (e.g. allergic skin reaction, anaphylaxis (severe allergic reaction))
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¹ Mild reactions up to 20 days after injection.

² Of the fascia or fat.

³ Unrelated to dose.

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: {national system details}

8. Dosage for each species, routes and method of administration

Pigs:

Intramuscular use.

3 mg ceftiofur/kg bw/day for 3 days by intramuscular injection, i.e. 1 ml of the product/16 kg bw/day.

Cattle:

Subcutaneous use.

Treatment of respiratory disease: 1 mg ceftiofur/kg bw/day for 3 to 5 days by subcutaneous injection, i.e. 1 ml of the product/50 kg bw/day.

Treatment of acute interdigital necrobacillosis: 1 mg ceftiofur/kg bw/day for 3 days by subcutaneous injection, i.e. 1 ml of the product/50 kg bw/day.

Acute post-partum metritis within 10 days after calving: 1 mg ceftiofur/kg bw/day for 5 consecutive days by subcutaneous injection, i.e. 1 ml of the product/50 kg bw/day.

Subsequent injections must be given at different sites.

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

9. Advice on correct administration

Shake the bottle well before use to bring the product back into suspension. In the case of 250 ml glass bottle, remove the protector before shaking. The coloration of the glass bottle may not be uniform making it difficult to determine when the product is in suspension. Following shaking the absence of sediment can be confirmed most readily by inverting the bottle and viewing the contents through the base of the bottle.

Should any apparent growth or discolouration occur, the product should be discarded.

To ensure a correct dosage, body weight should be determined as accurately as possible.

10. Withdrawal periods

Pigs:

Meat and offal: 5 days.

Cattle:

Meat and offal: 8 days.

Milk: zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Glass and PET bottles

Do not store above 25 °C.

Do not refrigerate or freeze.

PET bottles

Keep the PET bottles 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.

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

When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.

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 numbers and pack sizes

Pack sizes:

Cardboard box with 1 glass bottle of 50 ml.

Cardboard box with 1 glass bottle of 100 ml.

Cardboard box with 1 glass bottle of 250 ml.

Cardboard box with 10 glass bottles of 100 ml.

Cardboard box with 12 glass bottles of 100 ml.

Cardboard box with 1 PET bottle of 50 ml.

Cardboard box with 1 PET bottle of 100 ml.

Cardboard box with 1 PET bottle of 250 ml.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{DD/MM/YYYY}

Detailed information on this veterinary medicinal product is available in the [Union Product Database](https://medicines.health.europa.eu/veterinary) (<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:

LABORATORIOS HIPRA, S.A.

Avda. la Selva, 135

17170 Amer (Girona)

SPAIN

Local representatives and contact details to report suspected adverse events:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.