PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON – 50 ml, 100 ml or 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EXCENEL Fluid suspension (or EXCENEL Flow or Evo), 50 mg/ml, suspension for injection for pigs and cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains 50.0 mg/ml ceftiofur (as hydrochloride).

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

50 ml or 100 ml or carton containing 10 x 50 ml or 10 x 100 ml.
250 ml.

5. TARGET SPECIES

Pigs and cattle.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Before use, shake the bottle vigorously for a maximum of 60 seconds or until the product appears adequately resuspended.

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

Cattle: 1 mg ceftiofur /kg bw/day by subcutaneous injection, i.e. 1 ml/50 kg bw at each injection, for 3 to 5 days for respiratory disease, for 3 days for acute interdigital necrobacillosis and for 5 consecutive days within 10 days after calving for acute post-partum metritis.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Pigs: meat and offal: 2 days.
Cattle: meat and offal: 6 days; milk: zero hours.

9. SPECIAL WARNING(S), IF NECESSARY

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

Do not administer to an animal previously found to be hypersensitive to ceftiofur and other β -lactam antibiotics. Do not inject intravenously.

Special precautions for use in animals; Special precautions to be taken by the person administering the veterinary medicinal product to animals; Adverse reactions (frequency and seriousness); Use during pregnancy, lactation or lay: Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Date for discard:

Once broached use by 28 days.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25° C.

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 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

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4065

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING

VIAL –50 mL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EXCENEL Fluid suspension (or EXCENEL Flow or Evo) , 50 mg/ml, suspension for injection for pigs and cattle

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each ml contains 50.0 mg ceftiofur (as hydrochloride)

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

50 ml

4. ROUTES OF ADMINISTRATION

Dosage: Cattle: 1 mg ceftiofur/kg bwt/day given by subcutaneous injection.
Pigs: 3 mg ceftiofur/kg bwt/day given by intramuscular injection.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Pigs: meat and offal: 2 days.
Cattle: meat and offal: 6 days; milk: zero hours.

6. BATCH NUMBER

Lot [number}

7. EXPIRY DATE

EXP {month/year}

Date for discard:

Once broached use by 28 days.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

9. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4065

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

VIAL – 100 ml or 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EXCENEL Fluid suspension (or EXCENEL Flow or Evo) , 50 mg/ml, suspension for injection for pigs and cattle
Ceftiofur (as Ceftiofur hydrochloride).

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains 50.0 mg ceftiofur (as hydrochloride)

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

100, 250 ml or carton containing 10 x 50 ml or 10 x 100 ml.

5. TARGET SPECIES

Pigs and cattle.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Before use, shake the bottle vigorously for a maximum of 60 seconds or until the product appears adequately resuspended.

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

Cattle: 1 mg ceftiofur/kg bw/day by subcutaneous injection, i.e. 1 ml/50 kg bw at each injection.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Pigs: meat and offal: 2 days.
Cattle: meat and offal: 6 days; milk: zero hours.

9. SPECIAL WARNING(S), IF NECESSARY

Shake the bottle well before use to bring the product back into suspension.
Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Date for discard:

Once broached, use by 28 days.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25° C.

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

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 REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER

Vm 42058/4065

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PACKAGE LEAFLET

CY, EL, and IT
EXCENEL Fluid suspension, 50 mg/ml, suspension for injection for pigs and cattle

AT, DE, BE, LU, NL, FR, IE, SI and UK:
EXCENEL Flow, 50 mg/ml, suspension for injection for pigs and cattle

EE, LV, LT, PT and ES:
EXCENEL Evo, 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:

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

Manufacturer responsible for batch release:

Zoetis Belgium SA
rue Laid Burniat 1
1348 Louvain-la-Neuve
Belgium

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

EXCENEL Fluid suspension (or EXCENEL Flow or Evo) , 50 mg/ml, suspension for injection for pigs and cattle

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

Active substance:

Ceftiofur hydrochloride equivalent to 50.0 mg ceftiofur per ml.

Opaque suspension, white to off-white.

4. INDICATION(S)

Infections associated with bacteria sensitive to ceftiofur:

Pigs:
For the treatment of bacterial respiratory disease associated with P*asteurella multocida, Actinobacillus pleuropneumoniae* and *Streptococcus suis*.

Cattle:
For the treatment of bacterial respiratory disease associated with *Mannheimia haemolytica* (former *Pasteurella haemolytica*), *Pasteurella multocida* and *Histophilus somni* (former *Haemophilus somnus*).
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, were 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.

Do not inject intravenously.

Do not use in cases where resistance to other cephalosporins or beta-lactam antibiotics has occurred.

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) have been reported in very rare cases (less than 1 animal in 10,000 animals, including isolated reports).

In pigs, mild reactions at the injection site, such as discoloration of the fascia or fat, have been observed in very rare cases for up to 20 days after injection.

In cattle, firmness and swelling were observed at the injection site after SC injection of the test article. Mild to moderate local chronic inflammation was observed in most animals until 42 days post injection. Injection site reactions have been reported from the field in very rare cases.

If you notice any serious effects or other effects not mentioned in this package 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.
Not more than 4 ml should be administered per injection site.

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.
Not more than 13 ml should be administered per injection site.

9. ADVICE ON CORRECT ADMINISTRATION

Before use, shake the bottle vigorously for a maximum of 60 seconds or until the product appears adequately resuspended.

To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.

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

Subsequent injections must be given at different sites.

50 ml and 100 ml vials can be broached a maximum of 50 times. 250 ml vials can be broached a maximum of 33 times. Otherwise, the use of a multiple-dose syringe is recommended.

10. WITHDRAWAL PERIOD

Pigs: meat and offal: 2 days.

Cattle: meat and offal: 6 days; milk: zero hours.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 25° C.
Do not use this veterinary medicinal product after the expiry date stated on the label after EXP.
Shelf-life after first broaching of the container: 28 days.

12. SPECIAL WARNING(S)

Special precautions for use in animals

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

Do not use as prophylaxis in case of retained placenta.

EXCENEL Fluid suspension (or EXCENEL Flow or Evo) 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 limited to ongoing disease outbreaks according to the approved conditions of use. Inappropriate use of the product may increase the prevalence of bacteria resistant to cephalosporins.

Use of EXCENEL Fluid suspension (or EXCENEL Flow or Evo) may constitute a risk to public health due to spread of antimicrobial resistance.

EXCENEL Fluid suspension (or EXCENEL Flow or Evo) 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, EXCENEL Fluid suspension (or EXCENEL Flow or Evo) should only be used based on susceptibility testing.

Even though studies in laboratory animals show no evidence of teratogenesis, abortion or influence on reproduction, the reproductive safety of ceftiofur has not been specifically investigated in pregnant sows or cows. Use only according to a benefit/risk assessment by the responsible veterinarian.

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 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.

Wash hands after use.

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 Beta-lactams are neutralised by simultaneous use of bacteriostatic antibiotics (macrolides, sulfonamides and tetracyclines).

Aminoglycosides may have a potentiating effect on cephalosporins.

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 local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Legal category
Marketing authorisation number

This medicinal product is authorised in the Member States of the EEA under the following names:

Cyprus, Greece and Italy: EXCENEL Fluid suspension

Austria, Germany, Belgium, Luxembourg, Netherlands, France, Ireland, Slovenia and United Kingdom: EXCENEL Flow,

Estonia, Latvia, Lithuania, Portugal and Spain: EXCENEL Evo

EXCENEL Fluid suspension (or EXCENEL Flow or Evo) is supplied in 50, 100 or 250 ml vials. Not all pack sizes may be marketed.

Legal category: to be inserted.

Company logo

Approved 08 January 2020