# PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Cardboard box / 50 ml, 100 ml or 250 ml}

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EXCENEL Flow 50 mg/ml suspension for injection

## 2. STATEMENT OF ACTIVE SUBSTANCES

Ceftiofur 50 mg/ml.

## 3. PACKAGE SIZE

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

## 4. TARGET SPECIES

Pigs and cattle

## 5. INDICATIONS

## 6. ROUTES OF ADMINISTRATION

Pigs: intramuscular use.
Cattle: subcutaneous use.

## 7. WITHDRAWAL PERIODS

Withdrawal periods:
Pigs:
Meat and offal: 2 days.
Cattle:
Meat and offal: 6 days; milk: zero hours.

## 8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.
Use by…

## 9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.

## 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

Zoetis UK Limited

## 14. MARKETING AUTHORISATION NUMBERS

Vm 42058/5151(GB)

Vm 42058/3044 (NI)

## 15. BATCH NUMBER

Lot {number}

# PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {Vial / 100 ml or 250 ml}

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EXCENEL Flow 50 mg/ml suspension for injection

## 2. STATEMENT OF ACTIVE SUBSTANCES

Ceftiofur 50 mg/ml.

100 ml
250 ml

## 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

Withdrawal periods:
Pigs:
Meat and offal: 2 days.
Cattle:
Meat and offal: 6 days; milk: zero hours.

## 6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.
Use by…

## 7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.

## 8. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited

## 9. BATCH NUMBER

Lot {number}

# MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Vial / 50 ml}

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EXCENEL Flow

## 2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Ceftiofur 50 mg/ml.

50 ml

## 3. BATCH NUMBER

Lot {number}

## 4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.
Use by…

# PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

EXCENEL Flow 50 mg/ml suspension for injection for pigs and cattle

### 2. Composition

Each ml contains:

**Active substance:**
Ceftiofur (as hydrochloride) 50 mg.

Opaque suspension, white to off-white.

### 3. Target species

Pigs and cattle.

### 4. Indications for use

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*, *Pasteurella multocida* and *Histophilus somni*.
For the treatment of acute interdigital necrobacillosis (panaritium, foot rot), associated with *Fusobacterium necrophorum* and *Prevotella melaninogenica*.
For treatment of the bacterial component of acute post-partum (puerperal) metritis within 10 days after calving associated with *Escherichia coli*, *Trueperella pyogenes* and *Fusobacterium necrophorum*, sensitive to ceftiofur, where treatment with another antimicrobial has failed.

### 5. Contraindications

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

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. Special warnings

Special precautions for safe use in the target species:
In case of the occurrence of allergic reaction the treatment should be withdrawn.

Do not use as prophylaxis in case of retained placenta.

The veterinary medicinal product 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 veterinary medicinal product may increase the prevalence of bacteria resistant to cephalosporins.

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

The 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. Official, national and regional antimicrobial policies should be taken into account when the veterinary medicinal product is used. Increased use, including use of the veterinary medicinal product deviating from the instructions given, may increase the prevalence of resistance. Whenever possible, the veterinary medicinal 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 and penicillins should avoid contact with the veterinary medicinal product.

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:
Even though studies in laboratory animals show no evidence of teratogenesis, abortion or influence on reproduction, the safety of the veterinary medicinal product has not been established during pregnancy.
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, 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.

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 (e.g. allergic skin reaction, anaphylaxis), Injection site reaction (e.g. discolouration of fascia or fat)[1] |

[1]Mild, observed for up to 20 days.

Cattle:

| Very rare (<1 animal / 10,000 animals treated, including isolated reports): |
|---|
| Hypersensitivity reaction (e.g. allergic skin reaction, anaphylaxis), Injection site induration, Injection site swelling, Injection site inflammation[1] |

[1]Mild to moderate, observed until 42 days post 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 using the contact details at the end of this leaflet, or via your national reporting system at:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

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

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

Acute interdigital necrobacillosis: 1 mg ceftiofur/kg bw/day for 3 days by subcutaneous injection, i.e. 1 ml/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/50 kg bw/day.
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 veterinary medicinal product appears adequately resuspended.
To ensure a correct dosage, body weight should be determined as accurately as possible.
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 periods

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. The expiry date refers to the last day of the month.
Shelf life after first opening the immediate package: 28 days.

## 12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

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

Vm 42058/5151 (GB)
Vm 42058/3044 (NI)

Cardboard box containing 1 or 10 glass vial(s) of 50 or 100 ml.
Cardboard box containing 1 vial of 250 ml.

Not all pack sizes may be marketed.

## 15. PID LINK (Do not print heading)

*[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]*

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

## 16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP
Tel: +44 (0) 345 300 8034

Manufacturer responsible for batch release:
Zoetis Belgium
Rue Laid Burniat 1
1348 Louvain-La-Neuve
Belgium

## 17. Other information

POM-V

*Gavin Hall*
Approved: 14 March 2025