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Zactran 150mg/ml solution for injection for cattle, sheep and pigs [GB]

Species: Cattle

Therapeutic indication:Pharmaceuticals: Antimicrobials: Injections

Active ingredient: Gamithromycin

Product: Zactran 150 mg/ml Solution for Injection for cattle, sheep and pigs [GB]

Product index: Zactran [GB]

Cattle - milk: See note

Cattle - meat:64 days

Sheep - meat:29 days

Pig - meat:16 days

Withdrawal notes: Not authorised for use in lactating animals producing milk for human consumption.Do not use in pregnant animals which are intended to produce milk for human consumption within 2 months (cows, heifers) or 1 month (ewes) of expected parturition.

Incorporating:

Qualitative and quantitative composition

Each ml contains:

Active substance: Gamithromycin 150 mg

Excipient(s): Monothioglycerol 1 mg

For the full list of excipients, see below.

Pharmaceutical form

Solution for injection. Colourless to pale yellow solution.

Clinical particulars

Target species

Cattle, sheep and pigs.

Indications for use, specifying the target species

Cattle:

Treatment and metaphylaxis of bovine respiratory disease (BRD) associated with *Histophilus somni, Mannheimia haemolytica* and *Pasteurella multocida*.

The presence of the disease in the group should be established before the product is used.

Pigs:

Treatment of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae, Bordetella bronchiseptica, Glaesserella parasuis*, and *Pasteurella multocida*.

Sheep:

Treatment of infectious pododermatitis (foot rot) associated with virulent *Dichelobacter nodosus* and *Fusobacterium necrophorum* requiring systemic treatment.

Contra-indications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients or to other macrolide antibiotics. Do not use this veterinary medicinal product simultaneously with other macrolides or lincosamides (see '*Interactions*' section).

Special warnings for each target species

Cattle, pigs and sheep:

Cross resistance has been shown between gamithromycin and other macrolides. Use of the product should be carefully considered when susceptibility testing has shown resistance to other macrolides because its effectiveness may be reduced.

Avoid simultaneous administration of antimicrobials with a similar mode of action such as other macrolides or lincosamides.

Sheep:

The efficacy of antimicrobial treatment of foot rot might be reduced by other factors, such as wet environmental conditions, as well as inappropriate farm management. Treatment of foot rot should therefore be undertaken along with other flock management tools, for example providing dry environment. Antibiotic treatment of benign foot rot is not considered appropriate.

Special precautions for use:

Special precautions for use in animals

Use of the product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level. Use of the product should be in accordance with official, national and regional antimicrobial policies.

An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

People with known hypersensitivity to the macrolide class should avoid contact with the veterinary medicinal product. Gamithromycin may cause irritation to eyes and/or skin. Avoid contact with skin or eyes. If eye exposure occurs, flush eyes immediately with clean water. If skin exposure occurs, wash the affected area immediately with clean water.In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician. Wash hands after use.

Special precautions for the protection of the environment

Not applicable.

Other precautions

Not applicable.

Adverse reactions (frequency and seriousness)

Cattle:

Very common Injection site swelling1, injection site pai

(>1 animal / 10 animals treated)

1 Typically resolves within 3 to 14 days but may persist for up to 35 days

2 Slight pain may develop for 1 day

Sheep:

Common

Common Injection site swelling3, injection s

(1 to 10 animals / 100 animals treated)

3 Mild to moderate and typically resolves within 4 days

4 Slight pain may develop for 1 day

Pigs:

Common Injection site swellin

(1 to 10 animals / 100 animals treated)

5 Mild to moderate and typically resolves within 2 days

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.

Use during pregnancy, lactation or lay

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

Pregnancy:

Based on laboratory animal data, gamithromycin has not produced any evidence of specific developmental or reproductive effects.

Use only according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction

See Special Warnings for each target species section.

Amount(s) to be administered and administration route

A single dose of 6 mg gamithromycin/kg body weight (equivalent to 1 ml/25 kg body weight) into the neck (cattle and pigs) or anterior to the shoulder (sheep).

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

Cattle and sheep:

Subcutaneous injection. For treatment of cattle over 250 kg and sheep over 125 kg body weight, divide the dose so that no more than 10 ml (cattle) or 5 ml (sheep) are injected at a single site.

Pigs:

Intramuscular injection. The injection volume should not exceed 5 ml per injection site.

The cap may be safely punctured up to 50 times with a 16G needle and up to 80 times with a 18G needle. For multiple vial entry, an automatic dosing device is recommended to avoid excessive broaching of the stopper.

Overdose (symptoms, emergency procedures, antidotes), if necessary

Clinical studies have demonstrated the wide margin of safety for gamithromycin injection in the target species. In young adult cattle, sheep and pig studies, gamithromycin was administered by injection at 6, 18, and 30 mg/kg (1, 3, and 5 times the recommended dose) and repeated three times

at 0, 5 and 10 days (three times the recommended duration of use). Injection site reactions were noted in a dose related manner.

Withdrawal period(s)

Meat and offal:

Cattle: 64 days.

Sheep: 29 days.

Pigs: 16 days.

Not authorised for use in animals producing milk for human consumption. Do not use in pregnant animals which are intended to produce milk for human consumption within 2 months (cows, heifers) or 1 month (ewes) of expected parturition.

Classification of veterinary medicinal product

Veterinary medicinal product subject to prescription.

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

Pharmaceutical particulars

Excipients

Monothioglycerol, Succinic Acid, Glycerol Formal.

Major incompatibilities

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

Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

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

Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

Immediate packaging

Type 1 glass vial of 50, 100, 250 or 500 ml with a chlorobutyl rubber stopper, a polypropylene cap and an aluminium crimp seal.

Polypropylene vial of 100, 250 or 500 ml with a chlorobutyl rubber stopper, a polypropylene cap and an aluminium crimp seal.

Cardboard box containing 1 vial of 50, 100, 250 or 500 ml.

The 500 ml vial is for cattle and pigs only.

Not all pack sizes may be marketed.

Disposal

Medicines should not be disposed of via wastewater.

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

Marketing Authorisation Holder (if different from distributor)

Boehringer Ingelheim Vetmedica GmbH

Binger Strasse 173

55216 Ingelheim am Rhein

Germany

Marketing Authorisation Number

UK(GB): Vm 04491/5061

Significant changes

Legal category

Legal category:POM-V

GTIN

GTIN description: Zactran 150 mg/ml solution for injection 50 ml

GTIN:4028691567929

GTIN description: Zactran 150 mg/ml solution for injection 100 ml

GTIN:4028691564614

GTIN description: Zactran 150 mg/ml solution for injection 250 ml

GTIN:4028691575047