

Bilosin 200 Injection

Each ml contains

Active Substances

Tylosin Tartrate 200mg/ml

Excipients

Sodium Bisulfite 2 mg, Edetate Disodium 0.25 mg, Water for Injection



PHARMACEUTICAL PARTICULARS

Major incompatibilities

None known

Shelf-life Unopened:

3 years Broached:

28 days

Special precautions for storage

Do not store above 30°C.

Nature and contents of container

Multidose 50ml and 100ml glass vials sealed with a bromobutyl rubber stopper and capped with an over seals.

Special precautions for the disposal of unused veterinary medicinal products or waste materials

Unused product or waste material should be disposed off in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

Name or Corporate Name and Address or Registered Place of Business of the Marketing Authorisation Holder

Bimeda,
Broomhill Road,
Tallaght,
Dublin 24.





Special warnings for each target species.

Not Applicable

Withdrawal Period(s) Cattle

Meat: 35 days

Milk: 96 hours (at the eighth milking in cows milked twice daily).

Pigs

Meat: 21 days

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

Avoid skin contact with the preparation.

Wash hands after use.

Undesirable effects (frequency and seriousness)

Tolerance studies and toxicity studies suggest that undesirable effects are unlikely.

Occasionally swelling at the injection site may occur, but this effect is transient.

Product Development Rationale

Bilosin 200 is an antibacterial injection, which is a sterile solution, yellow in colour which contains Tylosin tartrate 200mg/ml.

Tylosin is a bacteriostat feed additive used in veterinary medicine. It has a broad spectrum of activity against Gram-positive organisms and a limited range of Gram-negative organisms.^[1] It is found naturally as a fermentation product of *Streptomyces fradiae*. It is a macrolide antibiotic.

Tylosin is used in veterinary medicine to treat bacterial infections in a wide range of species and has a high margin of safety. It has also been used as a growth promotant in some species, and as a treatment for colitis in companion animals

Amounts to be administered and administration route.

By intramuscular or subcutaneous injection Pigs: 10mg per kg body weight daily for 3days

Cow, calves: 10mg per body weight daily for 3-5days Sheep and

Goats: 10mg/kg body weight daily for 3 days

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

Contraindications:

Do not use in animals known to be hypersensitive to the active ingredient. It is recommended for horse.

Avoid skin contact with the preparation. Wash hands after use.

Undesirable effects.

Undesirable effects are unlikely. Occasionally swelling at the injection site may occur, but this effect is transient.

Withdrawal periods. Cattle Meat: 28 days

Milk: 96 hours (at the eighth milking in cows milked twice daily).

Pigs Meat: 21days.

Bimeda Ltd

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PHARMACEUTICAL FORM

Solution for Injection

PHARMACOLOGICAL PROPERTIES

Bilosin 200 Injection is an antibiotic preparation for intramuscular and subcutaneous administration. Tylosin is mainly effective against gram positive organisms, some gram negative bacteria, spirochaetes, mycoplasma and certain vibrios are also susceptible, and it is of particular value in swine dysentery. It is effective in treatment of calf pneumonia, swine pneumonia and mycoplasma infections in cattle, sheep and goats. It is also effective in treating infectious sinusitis due to *Mycoplasma gallisepticum*. restricted to the veterinary field and it is administered through intramuscular and subcutaneous.

CLINICAL PARTICULARS

Target Species

Pigs, Cattle Sheep and Goats.

Indications for use

Tylosin is mainly effective against gram positive organisms, some gram negative bacteria, spirochaetes, mycoplasma and certain vibrios are also susceptible, and it is of particular value in swine dysentery. It is effective in treatment of calf pneumonia, swine pneumonia and mycoplasma infections in cattle, sheep and goats. It is also effective in treating infectious sinusitis due to *Mycoplasma gallisepticum*.

Contraindications

Do not use in animals known to be hypersensitive to the active ingredient.

Special precautions for use

None

Use during pregnancy and lactation

Reports of adverse reproductive effects have not been noted during pregnancy.

Interaction with other medicinal products and other forms of interaction

Antagonism with penicillin and cephalosporin's.

Posology and method of administration

By intramuscular or subcutaneous injection:

Pigs: 10 mg per kg bodyweight daily for 3 days.

Cows, calves: 10 mg per kg bodyweight daily for 3 – 5 days.

To ensure a correct dosage bodyweight should be determined as accurately as possible.

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

Tolerance studies of up to 156% of the recommended dosage rate have been carried out with localized swelling at the injection site being the only adverse effect. The lowest recorded LD50 for tylosin from other acute toxicity studies was 400mg/ kg body weight (40 times the recommended dosage rate) by intravenous injection in mice.