RESTRICTED VETERINARY MEDICINE | KEEP OUT OF REACH OF CHILDREN
FOR ANIMAL TREATMENT ONLY

PenethaOne

Antibiotic Injection

5 MIU

DESCRIPTION:
Each clear glass vial contains 5,000,000 IU (5 MIU) penethamate hydriodide as a white to off-white, sterile powder. The accompanying 18 mL of diluent is drawn up and used to reconstitute the powder in the vial into a suspension prior to use.

MODE OF ACTION:
Penethamate hydriodide is a special ester of benzylpenicillin which is weakly basic (pKa 8.5) and lipophilic. The ester is capable of diffusing rapidly and effectively through cell membranes, producing high levels of antibiotic throughout the target tissue. The ester is resistant to beta-lactamase enzyme and transports the benzylpenicillin in a protected, intact form to the site of infection, where it is quickly hydrolysed to release the active bactericidal penicillin.

When in the plasma, penethamate is mainly present in the non-ionised form. The pharmacokinetic properties of PenethaOne ensure penetration of the mammary tissue even in inflamed quarters. The levels of penicillin in the milk of treated cows are up to 10 times higher than those achieved by other benzylpenicillin formulations at an equivalent dose, making the penethamate ester very suitable for the systemic treatment of mastitis.

Mechanisms of resistance:
The most frequent mechanism of resistance is production of beta-lactamase enzymes (more specifically penicillinase **especially by *S. aureus***), which break the beta-lactam ring of penicillins making them inactive.

Contraindications:
DO NOT administer by intravenous (IV) injection.

DO NOT use in animals that are known to be hypersensitive to penicillins or cephalosporins.

DO NOT administer to animals with renal disease including anuria or oliguria.

DO NOT administer to lagomorphs or small rodents.

Adverse Reactions:
In very rare cases, anaphylactic shock may occur.

INDICATIONS:
PenethaOne is indicated for the treatment of infections caused by penicillin-sensitive gram-positive bacteria that cause mastitis, metritis, respiratory infections and footrot in cattle.

Benzylpenicillin (penethamate hydriodide) is an antibiotic in the penicillin family and is considered highly important to human and animal health. The use of this antibiotic should only be for the minimum period needed to meet the clinical objective. Clinical response to this antibiotic should be monitored during treatment, and choice of therapy reviewed if clinical signs of disease persist, increase or relapse. In the event of treatment failure, culture and sensitivity should be considered to determine an appropriate alternative therapy. Indiscriminate use of this antibiotic can contribute to the development of antibiotic resistance.

DIRECTIONS FOR USE:
Reconstitute the powder contained in the vial by adding all the contents (18mL) of the diluent supplied. Shake well after reconstitution. Each 20mL of reconstituted suspension contains 5 MIU of penethamate.

Administer by intramuscular (IM) injection only, in the anterior half of the neck.

Use aseptic technique when withdrawing and administering each dose of PenethaOne.

Where local (regional, farm-level) epidemiological information indicates possible reduced susceptibility of the relevant strains of the bacterial species involved in mastitis, use of PenethaOne should be based on the susceptibility testing of bacteria isolated from diseased animals.

PenethaOne is not effective against beta-lactamase producing organisms.

Dosage:

1. **Cattle:** 5 MIU (20mL) once daily (equivalent to 10,000 - 15,000 IU/kg bodyweight/day). Repeat dose daily for 1 – 5 days.
2. For mastitis in lactating dairy cattle: Use the above dosing or alternatively give 10 MIU (40mL) on Day one, followed by 5 MIU (20mL) on Day two.

A maximum dosage volume of 20mL per injection site should be administered.

It is an offence for users of this product to cause residues exceeding the relevant MRL in the Food Notice: Maximum Residue Levels for Agricultural Compounds.

WITHHOLDING PERIOD:
Not for use in bobby calves.

MEAT (Cattle): Animals producing meat or offal for human consumption must not be sold for slaughter either during treatment or within 7 days of the last treatment.

MILK (Cattle): Milk intended for sale for human consumption must be discarded during treatment and for not less than: 48 hours after the last treatment of 5 MIU daily dosage; or 60 hours after the last treatment of 10 MIU plus 5 MIU.

WARNING - READ LABEL BEFORE USE

May cause an allergic skin reaction.

Very toxic to aquatic life with long lasting effects.

Handling Precautions:

Wear protective gloves when handling. Avoid breathing dust or spray.

Contaminated work clothing should not be allowed out of the workplace.

Wash contaminated clothing before reuse.

This product contains an ester of benzylpenicillin.

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.

First Aid:

IF ON SKIN: Wash with plenty of soap and water.

If skin irritation or rash occurs, get medical advice or attention.

Environmental Protection:

Avoid release to the environment.

Collect spillage.

Disposal:

Preferably dispose of product by use. Otherwise, dispose of product and packaging at an approved landfill or other approved facility.

STORAGE

Store below 25°C. Keep away from direct sunlight. The reconstituted aqueous suspension is stable for 12 hours at 25°C (room temperature) or for 7 days when stored between 2 – 8°C (refrigerated).

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Phone 0800 821 421

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