SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Penacare 300 mg/ml Suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:
Procaine Penicillin 300mg/ml (30% w/v)

Excipients:

Methyl parahydroxybenzoate 0.112%w/v (as preservative)
Ethyl parahydroxybenzoate 0.023%w/v (as preservative)
Propyl parahydroxybenzoate 0.016%w/v (as preservative)

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Suspension for Injection
A white/off-white suspension for injection

4. CLINICAL PARTICULARS

4.1. Target species

Cattle
Sheep
Pigs

4.2. Indications for use, specifying the target species

For the treatment of infections caused by or associated with organisms sensitive to penicillin.
In vitro tests have shown the following organisms to be sensitive: *Actinomyces pyogenes, Erysipelothrix rhusiopathiae, Listeria, Mannheimia haemolytica, Pasteurella multocida, Staphylococcus* spp (non-penicillinase producing) and *Streptococcus* spp.

Indicated in the treatment of diseases caused by susceptible organisms including:
erysipelas; navel/joint-ill; respiratory tract infections including pneumonia and atrophic rhinitis; listeriosis; septicaemia; urogenital tract infections and the control of secondary bacterial invaders in diseases of primary viral origin.

4.3. Contra-indications

Do not inject intravenously or intrathecally.
Do not use in known cases of hypersensitivity to penicillin.
Not to be used in very small herbivores such as guinea pigs, gerbils and hamsters.

4.4. Special Warnings for each target species

None.

4.5. Special precautions for use

i) Special precautions for use in animals

Care should be taken not to overdose.
Wherever possible, use of Penacare should be based on susceptibility testing.

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

Care should be taken to avoid accidental self-injection.
Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillin's may lead to cross reactions to cephalosporin's and vice versa. Allergic reactions to these substances may occasionally be serious.

1. Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.
2. Handle this product with great care to avoid exposure, taking all recommended precautions.
3. 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.

4.6. Adverse reactions (frequency and seriousness)

Occasionally in sucking and fattening pigs, administration may cause a transient pyrexia, vomiting, shivering, listlessness and inco-ordination.

4.7. Use during pregnancy, lactation or lay

Can be safely administered to pregnant and lactating animals. However in pregnant sows and gilts a vulval discharge which could be associated with abortion has been reported.

4.8. Interaction with other medicinal products and other forms of interaction

It is recommended that other antibiotics should not be administered concurrently.

4.9. Amounts to be administered and administration route

Shake the container before use.
Administer by deep intramuscular injection only.
The recommended dose rate is: 10 mg/kg bodyweight (1ml/30 kg) daily for 3 to 5 days.

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

Penicillins have a wide safety margin.

4.11. Withdrawal periods

Cattle: Meat – 7 Days
Milk – 84 Hours

Sheep: Meat: 7 Days
Milk: Not permitted for use in sheep producing milk for human consumption.

Pigs: Meat – 7 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterial
ATCVet Code: QJ01CE09

5.1. Pharmacodynamic properties

Antimicrobial activity is achieved by interference in the final stage of bacterial cell wall synthesis by binding to the PBP's (penicillin binding proteins).

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Methyl parahydroxybenzoate
Ethyl parahydroxybenzoate
Propyl parahydroxybenzoate
Povidone K12,
Potassium Dihydrogen Phosphate,
Sodium Citrate Dihydrate,
Polysorbate 80,
Simeticone,
Water for injections.

6.2. Incompatibilities

None known.

6.3. Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life after first opening the immediate packaging: 28 days.

6.4. Special precautions for storage

Do not store above 25 ^{o}C.
Protect from light.
Following withdrawal of the first dose, use the product within 28 days.
Discard unused suspension.

6.5. Nature and composition of immediate packaging

Sterile, white aqueous injection in clear Type II multidose glass vials of 50 ml and 100 ml closed with bromobutyl bungs with aluminium overseals.
Not all pack sizes may be marketed.

6.6. Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

Listow Limited
9 Belgrave Square
London
SW1X 8PH

8. MARKETING AUTHORISATION NUMBER

Vm: 41687/4015

9. DATE OF FIRST AUTHORISATION

Date: 1 June 1998

10. DATE OF REVISION OF THE TEXT

Date: May 2014


06 May 2014