

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Potencil 10% premix for medicated feed for pigs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Phenoxyethylpenicillin potassium (penicillin V) 10.0% w/w in an inert carrier.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Premix for medicated feed

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs.

4.2 Indications for use, specifying the target species

For the treatment and control of Streptococcal meningitis and septicaemia caused by *Streptococcus suis* II. Also for the treatment and control of porcine pleuropneumonia caused by *Actinobacillus (Haemophilus) pleuropneumoniae*, and treatment and control of secondary bacterial pneumonia caused by *Pasteurella multocida*

4.3 Contraindications

Do not use in liquid feed.

Do not use for direct feeding to animals.

Do not use in animals known to be hypersensitive to penicillins.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Care must be taken to ensure accurate mixing.

Avoid the introduction of contamination during use.

Special precautions for 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.

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

Wear protective clothing, gloves and a dust mask, either a disposable half-mask respirator conforming to European Standard EN 149 or a non-disposable respirator to European Standard EN 140 with a filter EN143 when preparing medicated feed.

If you develop symptoms following exposure such as skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty in breathing are more serious symptoms and require urgent medical attention.

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Studies to determine the safety of this product for use during pregnancy have not been conducted in pigs. Use in pregnant pigs should be in accordance with a benefit/risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For oral administration after incorporation in pelleted feed or meal. The recommended dosage for pigs is 10 mg potassium penicillin per kg bodyweight daily for up to 6 consecutive weeks for meningitis and septicaemia, and for up to 2 weeks for pleuropneumonia and pneumonic pasteurellosis. This is achieved by an inclusion level of 2 kg Potencil/tonne of feed.

When incorporated into pellets, the mix can be pre-conditioned with steam for up to 5 minutes and pelleted at temperatures within the feed of 70°C.

To allow thorough dispersion of the product, Potencil should be mixed with a small quantity of feed prior to mixing into the bulk of the feed.

After inclusion of Potencil, feed must be used within 14 days from manufacture, due to the known instability of Potencil.

This product should be incorporated by a licensed feed manufacturer only.

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

None known.

4.11 Withdrawal Period(s)

Pigs must not be slaughtered for human consumption during treatment or for 24 hours (1 day) thereafter.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC Vet Code: QJ01CE02

5.1 Pharmacodynamic properties

Beta-lactam antibiotics, such as the penicillins, prevent the bacterial cell wall from forming by interfering with the final stage of peptidoglycan synthesis. They inhibit the activity of transpeptidase enzymes which catalyze cross-linkage of the glycopeptide polymer units that form the cell wall. The final step in the action of these substances probably involves inactivation of an inhibitor of autolytic enzymes in the cell wall. They exert a bactericidal action, but cause lysis only of growing cells.

5.2 Pharmacokinetic properties

The penicillins are organic acids that are generally available as the sodium or potassium salt of the free acid. Acid hydrolysis limits the systemic availability of most penicillins from oral preparations, but not penicillin V. Penicillins (pK 2.7) are predominantly ionized in plasma, have relatively small apparent volumes of distribution (0.2 -0.3 L/kg) and have short half lives (0.5 -1.2 hours) in domestic animals. After absorption, they are widely distributed in the extracellular fluids of the body, but they cross biological membranes poorly as they are ionized and are poorly soluble in lipids. Entry across biological membranes or through the blood-brain or blood-cerebrospinal fluid barrier is enhanced by inflammation, so that inhibitory drug concentrations may be attained at these sites that are normally inaccessible to penicillin.

Penicillins are eliminated almost entirely by the kidneys which results in very high levels in the urine.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid Paraffin
Limestone

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.

Shelf-life when incorporated into feed: 14 days.

6.4 Special precautions for storage

Do not store above 25°C. Store in a dry place.

6.5 Nature and composition of immediate packaging

Pack size: 2 kg, 3 kg and 6 kg
Container: 2 ply low density polyethylene lined multi-walled paper bag
Closure: Heat seal

Pack size: 25 kg
Container: 3 ply low density polyethylene lined multi-walled paper sack
Closure: LDPE liner closed with plastic coated metal closure. Paper sack is stitched.

Not all pack sizes may be marketed.

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

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

VPA 10397/023/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st May 2001
Renewal of the last authorisation: 1st May 2006

10 DATE OF REVISION OF THE TEXT

June 2016