

**ANNEX III**  
**LABELLING**

## **A. LABELLING**

## PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

**NATURE/TYPE:** low density polyethylene lined multi-walled paper bag

### 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Potencil 10% Premix for medicated feed

### 2. STATEMENT OF ACTIVE SUBSTANCES

#### PRESENTATION

A grey, free flowing powder for incorporation into animal feed, containing 10% phenoxymethylpenicillin potassium (100 g/kg).

### 3. PHARMACEUTICAL FORM

#### Potencil

Premix for medicated feed.

### 4. PACKAGE SIZE

2 kg  
25 kg

### 5. TARGET SPECIES

Pigs

### 6. INDICATION(S)

#### USES

For the treatment and control of streptococcal meningitis and septicaemia caused by *Streptococcus suis* II in pigs. 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*.

#### FURTHER INFORMATION

On commercial pig farms, Potencil has been shown to be very effective in the control and treatment of streptococcal meningitis/septicaemia and control of *Actinobacillus pleuropneumoniae* and *Pasteurella multocida* infections.

### 7. METHOD AND ROUTE(S) OF ADMINISTRATION

#### DOSAGE AND ADMINISTRATION

For oral administration after incorporation in pelleted feed or meal at an inclusion level of 2 kg Potencil per tonne of feed. This is approximately equivalent to 10 mg phenoxymethylpenicillin potassium per kg bodyweight daily.

To be fed *ad-libitum* for up to 6 consecutive weeks for meningitis/septicaemia, and up to 2 weeks for pleuropneumonia/pneumonic pasteurellosis. Freshly manufactured medicated diet should be supplied every 2 weeks.

To allow thorough dispersion of the product, Potencil should be mixed with a small quantity of feed ingredients prior to mixing into the bulk of the feed. In pelleting, the mix can be pre-conditioned with steam for up to 5 minutes and processed at temperatures in the feed of up to 70°C. After incorporation under these conditions, Potencil retains satisfactory activity for 2 weeks. Accurate mixing is essential. Avoid the introduction of contamination during use.

## 8. WITHDRAWAL PERIOD(S)

### WITHDRAWAL PERIOD:

Animals must not be slaughtered for human consumption during treatment. Pigs may be slaughtered for human consumption only after 24 hours (1 day) from the last treatment.

## 9. SPECIAL WARNING(S), IF NECESSARY

### CONTRA-INDICATIONS, WARNINGS:

Not for direct feeding. Not for use in liquid feed. Not for use in animals known to be hypersensitive to penicillins.

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.

Not for handling by operatives with known sensitivity to penicillins.

**Operator Warnings:** 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. Skin sensitisation may occur, care should be taken to avoid direct skin contact by wearing protective clothing, gloves and a dust mask, either a disposable half-mask respirator conforming to European Standard EN149 or a non-disposable respirator to European Standard EN140 with a filter to EN143, when preparing medicated feed. 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.

## 10. EXPIRY DATE

EXP {month/year}

After inclusion of Potencil, feed must be used before the end of a fourteen-day period from manufacture, due to loss of potency of the active ingredient.

## 11. SPECIAL STORAGE CONDITIONS

### PHARMACEUTICAL PRECAUTIONS

Store in a dry place. Do not store above 25°C. Close container after use.

## 12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

**Disposal:** Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

## 13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

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

Veterinary Medicinal Product authorised for use in UK and IE.

UK: POM-V

IE: POM Prescription Only Medicine

## 14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the reach and sight of children.

## 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

**Elanco Europe Ltd.**,  
Lilly House, Priestley Road,  
Basingstoke, Hampshire,  
RG24 9NL, UK.  
Tel: 01256 353131

### Manufacturer for the batch release:

Eurovet Animal Health B.V.  
Handelsweg 25  
5531 AE  
Bladel, Netherlands

## 16. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4034  
VPA 10397/023/001


## 17. MANUFACTURER'S BATCH NUMBER

BN {number}

## **B. PACKAGE LEAFLET**

There is no package leaflet for Potencil, 10% premix for medicated feed for pigs as all the information required is included on the label.

**Approved: 26/04/2017**

A handwritten signature in black ink, appearing to read 'J. Berg', is written below the approval date.