IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007

(S.I. No. 786 of 2007)

VPA: **10996/034/001**
Case No: 7003310

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

Intervet Ireland Limited

Magna Drive, **Magna Business Park**, **Dublin 24**, **Ireland**

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Pen V Intervet premix for medicated feedingstuff

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

The authorisation, unless previously revoked, shall continue in force from **30/09/2007**.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: From this date of effect, this authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Pen V Intervet premix for medicated feedingstuff

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance

Phenoxymethylpenicillin Potassium	100% w/w

3 PHARMACEUTICAL FORM

Premix for medicated feedingstuff
A white or almost white, crystalline powder.

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs.

4.2 Indications for use, specifying the target species

The product is indicated for the treatment of penicillin sensitive infections, in particular streptococcal meningitis.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient

4.4 Special warnings for each target species

None

4.5 Special precautions for use

Special precautions for use in animals
During treatment ensure that medicated feed only is fed. Since Penicillin V Potassium is unstable at high temperatures, the product should not be included in pelleted feeds where the temperature exceeds 55^{o}C.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Handle this product with great care and avoid direct skin contact. Take all recommended precautions by wearing protective clothing, gloves and a dust mask when preparing medicated feed. Skin sensitivity has been known to occur in persons handling penicillin.

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact.
Hypersensitivity to penicillin may lead to cross-sensitivity to cephalosporins and vice versa. Allergic reactions to these substances are occasionally 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. 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 breathing are
more serious symptoms and require urgent medical attention.

4.6 Adverse reactions (frequency and seriousness)

Occasional allergies to penicillin have been reported but these are very rare.

4.7 Use during pregnancy, lactation or lay

No special precautions.

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 by inclusion in feedingstuffs.
The dosage rate is 20-30mg penicillin V potassium per kg bodyweight per day. This is obtained by mixing 200g Pen V-Intervet per tonne of complete feed. To help obtain uniform dispersal first mix the required amount of product with ten times its weight of feed ingredient before blending into the final mix. The maximum recommended duration of treatment is seven days.
This product should be incorporated by licensed feed manufacturers only.

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

Penicillin is a compound with a very high therapeutic ratio. It is very unlikely that an overdose of the product will have adverse effects on the treated animals.

4.11 Withdrawal Period(s)

Meat and offal: 3 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Antibacterials for systemic use, Beta-lactamase sensitive penicillins.
ATC Vetcode: QJ01CE02.

5.1 Pharmacodynamic properties

The product contains Penicillin V, a bacterial antibiotic with activity against a range of Gram-positive bacteria. The antibacterial action is achieved by preventing bacterial cell wall synthesis and disrupting the integrity (lysis) of growing bacterial cells.

5.2 Pharmacokinetic properties

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None

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 incorporation into meal feed: 14 days.

6.4 Special precautions for storage

Store in a closed container.
Do not store above 25°C.

6.5 Nature and composition of immediate packaging

Sealed polythene bags to contain 25kg of product in multiwall paper sacks.

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

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

7 MARKETING AUTHORISATION HOLDER

INTERVET IRELAND Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24

8 MARKETING AUTHORISATION NUMBER(S)

10996/ 10996/34/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2002 / 30th September 2007