IRISH MEDICINES BOARD ACT 1995

ANIMAL REMEDIES REGULATIONS, 2005

(S.I. No. 734 of 2005)

VPA: **10835/003/001**
Case No: 7001570

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies Regulations (S.I. No. 734 of 2005) hereby grants to:

Novartis Animal Health

Industrial Park, **Cork Road**, **Waterford**

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:

Pevidine 1% Antiseptic Cutaneous Solution

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.

Signed on behalf of the Irish Medicines Board this

_____

A person authorised in that behalf by the said Board.

(NOTE: 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

Pevidine 1% Antiseptic Cutaneous Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance

Povidone-Iodine 1.0 w/v%

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous solution.

4 CLINICAL PARTICULARS

4.1 Target Species

For general use in animals.

4.2 Indications for use, specifying the target species

Pevidine Antiseptic Solution is for use as a topical antiseptic in the disinfection of operation sites in all species.

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

Heavily contaminated sites should first be cleaned with Pevidine Surgical Scrub before application of Pevidine Antiseptic Solution.

Pevidine Antiseptic Solution may exacerbate metabolic acidosis in animals predisposed to this condition when cleaning areas of abraded or missing skin totalling more than 20% of the body surface area.

Special Precautions to be taken by the Person Administering the Medicinal Product to Animals

Splashes into the eye should be dealt with by irrigating the eye with copious quantities of clean water.

4.6 Adverse reactions (frequency and seriousness)

The remote possibility of a hypersensitivity reaction should be borne in mind. Should such a reaction occur wash the site of application and treat symptomatically.

4.7 Use during pregnancy, lactation or lay

This product can be used in pregnant and lactating animals.

There are no precautions specific to such use.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For topical administration only.

Apply undiluted to operation site before surgery.

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

Unlikely to occur in practice.

4.11 Withdrawal Period(s)

Edible tissues from slaughtered animal: 1 day.
Milk: 24 hours.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Topical disinfectant/antiseptic.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerine
Emipilan NP9
Sodium hydroxide solution
Disodium hydrogen phosphate
Citric acid, anhydrous
Purified Water

6.2 Incompatibilities

The antiseptic activity of Povidone-Iodine is reduced by alkalis.

6.3 Shelf-life

3 years

6.4 Special precautions for storage

Store below 25ºC.

6.5 Nature and composition of immediate packaging

Polyethylene containers holding a brown aqueous solution, closed with a LDPE screw cap.

Volume: 500 ml or 5 litres.

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

Novartis Animal Health Ireland Ltd.,
Industrial Park,
Cork Road,
Waterford.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10835/3/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2003