IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10956/008/003**
Case No: 7003018

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:

Ballinskelligs Vet. Products Ltd

Ballinskelligs, **Co. Kerry**, **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:

B.V.P. Barium Selenate Injection

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 **30/09/2008**.

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

B.V.P. Barium Selenate Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substances:	
Selenium	50 mg/ml
(as Barium Selenate 177.48 mg/ml)	
Excipients:	
Chlorocresol	2 mg/ml

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Suspension for injection.
A white sterile aqueous suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle.

4.2 Indications for use, specifying the target species

For the treatment and prevention of selenium deficiency in cattle.

4.3 Contraindications

Do not overdose.
Do not administer intravenously or intramuscularly.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Use aseptic technique.

Special precautions to be taken by the person administering the product to animals

Self-inoculation could cause serious localised reactions.
If accidental injection occurs the person is instructed to go at once to the nearest hospital, as special emergency treatment may be necessary and to take with them the pack insert to show the doctor, who should be informed that this is an oil based product.

4.6 Adverse reactions (frequency and seriousness)

Allergic reactions occur occasionally to selenium.
Local tissue reaction may occur at the site of infection but this will be transient and disappear in less than one month.

4.7 Use during pregnancy, lactation or lay

This product may be used safely in pregnant and lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

Do not use simultaneously with any other preparation.

4.9 Amounts to be administered and administration route

Shake the vial vigorously to re-suspend the solid prior to use.
Inject into a clean site in the neck area by subcutaneous injection only, using aseptic technique. Actual dose will depend on the selenium status and clinical condition of the animal. As a guide it is suggested that a dose of 1mg Se/kg bodyweight be used corresponding to the following:

Cattle (adult):	6-10 ml
Cattle (young):	3-8 ml
Calves:	1-2 ml

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

Overdosage with this product is unlikely as its characteristics are for slow release of selenium, in selenium deficient animals under the instructions of a veterinary practitioner.

4.11 Withdrawal Period(s)

Meat and Offal: 31 days
Milk: Zero days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

The product is recommended for the treatment of selenium deficiency in cattle. The product will provide a prolonged rise in the selenium status in animals, lasting up to twelve months. The treatment of animals in early to mid-pregnancy will provide a good selenium status in the newly born offspring.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chlorocresol
Light Liquid Paraffin
Glycerol Monostearate
Water for Injection

6.2 Incompatibilities

Do not use simultaneously with any other preparation.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf-life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Do not store above 25^{o}C.

6.5 Nature and composition of immediate packaging

An amber Type II glass, 100ml vial, with a nitryl rubber bung and gold coloured aluminium seal.

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

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

7 MARKETING AUTHORISATION HOLDER

Tairgi Tread-Lia Baile na Sceilge Teo,
Ballinskelligs,
Killarney,
Co. Kerry,
Ireland.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10956/008/003

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2001./ 30th September 2006