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 precaution(s) for use in animals
Use aseptic technique.

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

To the user:
This product contains mineral oil. Accidental injection/self injection may result in severe pain and swelling, particularly if injected into a joint or finger and in rare cases could result in the loss of the affected finger if prompt medical attention is not given.
If you are accidentally injected with this product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you.
If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This product contains mineral oil. Even if small amounts have been injected, accidental injection with the product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

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

The 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. The actual dose will depend on the selenium status and clinical condition of the animal. The recommended treatment dose is 1mg Se/kg bodyweight corresponding to 1 ml per 50 kg bodyweight. The following is a guide to the maximum doage:

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

To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid overdosing.
Do not administer more than 10 ml.
Check selenium status of animals before re-treating.
Inject **subcutaneously only** using an appropriate injection technique to avoid intramuscular injection.

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
Stearoyl Macroglycerides
Sodium Hydroxide (for pH adjustment)
Hydrochloric Acid (for pH adjustment)
Water for Injections

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, 50ml 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

Ballinskelligs Vet. Products Ltd,
Ballinskelligs,
Killarney,
Co. Kerry,
Ireland.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10956/008/002

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2006

10 DATE OF REVISION OF THE TEXT

May 2012