

**IRISH MEDICINES BOARD ACT 1995**

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

**(S.I. No. 786 of 2007)**

VPA:10825/025/001

Case No: 7000077

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:

**Novartis Animal Health UK Ltd**

**Frimley Business Park, Frimley, Surrey GU16 7SR, England**

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:

**Deposel Multidose 50 mg/ml Suspension for 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 Part 2 of the said Schedule.

This authorisation, unless previously revoked, shall continue in force from **16/04/2010** to **15/04/2015**.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Deposel Multidose 50 mg/ml Suspension for Injection

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

**Active ingredients:**

Selenium (as barium selenate 175 mg/ml)      50 mg/ml

**Excipients:**

Methyl parahydroxybenzoate	2 mg/ml
Propyl parahydroxybenzoate	0.5 mg/ml
Potassium sorbate	2 mg/ml
Disodium edetate	2 mg/ml
Ferric oxide, yellow (E172)	3 mg/ml

For a full list of excipients, see section 6.1.

#### 3 PHARMACEUTICAL FORM

Suspension for injection.

Smooth, yellow aqueous suspension.

#### 4 CLINICAL PARTICULARS

##### 4.1 Target Species

Cattle and sheep.

##### 4.2 Indications for use, specifying the target species

For the treatment and prevention of selenium deficiency in sheep and cattle for up to 12 months.

##### 4.3 Contraindications

None.

##### 4.4 Special warnings for each target species

Do not exceed the recommended dosage.

## 4.5 Special precautions for use

### i) Special precautions for use in animals

Shake pack well before use to ensure resuspension of contents. It is advisable to establish the selenium status of animals prior to treatment.

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

Care should be taken to avoid accidental self-injection.

Wash hands after use.

## 4.6 Adverse reactions (frequency and seriousness)

A nodule is likely to develop at the injection site as a depot of the barium selenate administered. During the clinical studies, indication of transient pain in cattle at the injection site was noted during the first week.

## 4.7 Use during pregnancy, lactation or lay

No specific warnings.

## 4.8 Interaction with other medicinal products and other forms of interaction

None known.

## 4.9 Amounts to be administered and administration route

For subcutaneous injection only into the neck area.

1 ml per 50 kg bodyweight, equivalent to 1 mg selenium per kg bodyweight. The following table is intended as a guide:

Lambs at weaning	0.5 ml
Sheep	1– 2 ml
Calves	1– 2 ml
Young cattle	3 – 8 ml
Adult cattle	6 – 10 ml

When treating a large number of animals, a suitable multiple dose injector must be used.

Shake pack well before use to ensure resuspension of contents.

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

Overdose should be avoided, as there is no known antidote.

## 4.11 Withdrawal Period(s)

Cattle- meat: zero days  
- milk: zero hours

Sheep- meat: zero days  
- milk: zero hours

The injection site should be removed at slaughter, and is easily identified by the discolouration caused by the yellow ferric oxide in the product.

## 5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Alimentary tract and metabolism, other mineral supplements, selenium combinations.

ATCvet code QA12CE99

### 5.1 Pharmacodynamic properties

Selenium is an essential constituent of at least two enzymes:

*Glutathione peroxidase* which is involved in the control of lipid peroxides which, if allowed to accumulate, disrupt cell membranes leading to cell death and muscle degeneration. A deficiency of this enzyme will cause symptoms which can include myopathy, reduced growth rate, increased incidence of disease, and reproductive disorders which may include infertility, abortion and stillbirth.

*Iodothionine iodinase* which is needed for the production of active thyroid hormone

### 5.2 Pharmacokinetic properties

Deposel Multidose provides a subcutaneous depot of selenium as barium selenate, a salt of low solubility. This selenium is absorbed slowly over a period of one year and thereby enables the animal to maintain an adequate level of specific enzymes.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Methyl parahydroxybenzoate  
Propyl parahydroxybenzoate  
Potassium sorbate  
Disodium edetate dihydrate  
Ferric oxide, yellow (E172)  
Macrogol 400  
Polysorbate 80  
Xanthan gum  
Water for injection

### 6.2 Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product should not be mixed with other veterinary medicinal products.

### 6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years

Shelf life after first opening of the immediate packaging: 28 days

### 6.4 Special precautions for storage

Do not store above 25°C. Protect from light.

6.5 Nature and composition of immediate packaging

Type:	Natural low density polyethylene bottle
Sizes:	100, 250 and 500 ml
Closure:	Chlorobutyl rubber stopper and aluminium overseal

Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste material derived from the use of such veterinary medicinal products should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Novartis Animal Health UK Limited  
Frimley Business Park  
Frimley,  
Camberley  
Surrey,  
GU16 7SR  
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10825/025/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

16<sup>th</sup> April 2010

10 DATE OF REVISION OF THE TEXT