Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Vitesel Suspension for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substances		
all-*rac*-α-Tocopheryl acetate	68	mg
Selenium (as Potassium selenate)	1.5	mg

Excipients:		
Benzyl alcohol	20	mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Suspension for injection.

A white suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs, Lambs (new born and older lambs), Calves, Ewes.

4.2 Indications for use, specifying the target species

Vitesel is indicated for the prevention and treatment of Vitamin E/selenium deficiency syndrome in pigs, lambs and calves, including the various manifestations of nutritional muscular dystrophy (white muscle disease). Administration of Vitesel to the pregnant ewe may assist in the prevention of the deficiency syndrome in the new born lamb under similar conditions.

4.3 Contraindications

Do not use in animals known to be hypersensitive to the active substance.
Do not use in pregnant cattle.

4.4 Special warnings for each target species

None

4.5 Special precautions for use

Special precautions for use in animals
None known.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
None.

4.6 Adverse reactions (frequency and seriousness)

A mild and transient injection site reaction may occur.

Allergic-type reactions may occur.

4.7 Use during pregnancy, lactation or lay

Vitesel can be safely administered to pregnant sheep. Not for use in lactating animals

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

Vitesel is administered by subcutaneous or intramuscular injection.

Pigs:
1 ml per 25 kg (55lb) bodyweight (i.e., 2.72 mg vitamin E, 0.06 mg selenium per kg bwt). Repeat after 2-4 weeks if required.

Lambs:
Newborn: 0.5 ml. (i.e., 34 mg vitamin E, 0.75 mg selenium per animal). Repeat after 2-4 weeks if required.

Older lambs: 0.5-1 ml. (i.e., 34-68 mg vitamin E, 0.75-1.5 mg selenium per animal). Repeat after 2-4 weeks if required.

Calves:
1-2 ml per 45 kg (100lb) bodyweight (i.e., 1.5-3.0 mg vitamin E, 0.03-0.06 mg selenium per kg bwt). Repeat after 2-4 weeks if required.

Ewes:
2 ml per 45 kg (100lb) bodyweight after third month of pregnancy (i.e.3.0 mg vitamin E, 0.06 mg selenium per kg bwt).

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

Animals suffering from acute, high level selenium toxicosis following overdosage with parenteral selenium supplements may present with severe respiratory distress, watery diarrhoea, fever, tachycardia and abnormal posture and gait followed by recumbency and death after a short illness. In pigs, overdosage may produce fatal acute selenium toxicosis manifested by vomiting, respiratory distress, weakness, central nervous system (CNS) depression, coma and death. Mildly affected pigs may show a posterior ataxia, walk on tiptoe and may be in sternal recumbency but able to rise.

4.11 Withdrawal period(s)

Foodstuffs must not be taken for human consumption during the treatment period.

Edible tissues
Calves, Pigs, Sheep: 28 days
Milk:Not permitted for use in lactating sheep producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Vitamin E and selenium function in biological systems primarily as antioxidants and as anti free-radical agents, particularly for the unsaturated fatty acids in the phospholipids of cell membranes. It has been postulated that these two components act in a synergistic manner to maintain cellular integrity

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol
Polysorbate 80
Sodium dihydrogen phosphate dehydrate

Disodium phosphate dodecahydrate
Water for injections

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 18 months.
Shelf-life after first opening the immediate packaging: 28 days

6.4 Special precautions for storage

Store below 25°C.
Protect from light

6.5 Nature and composition of immediate packaging

Vitesel is marketed in 50 ml Type II glass vials (amber) sealed with bromobutyl bungs (grey) and aluminium caps.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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

7 MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22664/034/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 1991
Date of last renewal: 30 September 2006

10 DATE OF REVISION OF THE TEXT

January 2019