SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vitesel Emulsion for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Alpha-Tocopheryl Acetate	68 mg/ml
Selenium (as Potassium Selenate)	1.5 mg/ml

Excipients:

Benzyl alcohol as antimicrobial preservative	20 mg/ml

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Emulsion for Injection.
A white emulsion free from visable particles.

4. CLINICAL PARTICULARS

4.1 Target species

Ewes
Piglets
Lambs (new born and older lambs)
Calves

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

None.

4.4 Special Warnings for each target species

Hypersensitivity reactions, particularly in cattle, have occasionally been reported following use of this product. In such an event, symptomatic treatment should be undertaken as appropriate.

4.5 Special precautions for use

Special precautions for use in animals

Observe aseptic precautions.
Shake vial before use.

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

Care should be taken to avoid accidental self-injection.

4.6 Adverse reactions (frequency and seriousness)

Injection site reactions may occur in some animals. These are usually of a transient nature and diminish after a few days.

4.7 Use during pregnancy, lactation or lay

Can be safely administered to pregnant and lactating sheep.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Administer by intramuscular injection only to piglets and calves.

Piglets:	1 ml per 25 kg bodyweight Repeat after 2-4 weeks if required.
Calves:	1-2 ml per 45 kg bodyweight. Repeat after 2-4 weeks if required.

Administer by subcutaneous or intramuscular injection to lambs and by subcutaneous injection only to ewes.

Ewes:	2 ml per 45 kg bodyweight after third month of pregnancy. (For protection of lambs against deficiency).
Newborn Lambs:	0.5 ml. Repeat after 2-4 weeks if required.
Older lambs:	0.5-1 ml. Repeat after 2-4 weeks if required.

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

Excess selenium may cause blind staggers or alkali disease with ataxia and affections of hair and hooves. Treatment is symptomatic.

4.11 Withdrawal period

Piglets, Lambs and Calves:	Meat = Zero days.
Ewes:	Meat = 28 days.

The product should not be administered to ewes producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Vitamins
ATC Vet Code: QA11JB

5.1 Pharmacodynamic 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.

5.2 Pharmacokinetic properties

Vitamin E is absorbed from the gastro-intestinal tract, entering the bloodstream via the lymph gland where it is widely distributed throughout the body. The highest concentrations of Vitamin E are found in the liver, plasma and adipose tissue. Selenium is absorbed mainly in the duodenum before being distributed throughout the body.
Excretion occurs through the urine and/or faeces and appears to be dependant on a renal threshold.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl Alcohol
Polysorbate 80
Disodium Phosphate Dihydrate
Sodium Dihydrogen Phosphate Dihydrate
Water for Injections

6.2 Incompatibilities

None Known

6.3 Shelf life

Shelf life of the veterinary product as packaged for sale: 2 Years.
Shelf life after first opening the immediate packaging: 28 Days.

6.4 Special precautions for storage

Do not store above 25ºC.
Protect from light.
Following withdrawal of the first dose, use the product within 28 days. Discard unused material.

6.5 Nature and composition of immediate packaging

Vitesel is a white sterile emulsion, marketed in 50 ml amber glass type II vials, sealed with bromobutyl bungs and aluminium caps.

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

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

7. MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Newry
Co. Down, BT35 6JP
Northern Ireland

8. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4115

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 18 June 1993

10. DATE OF REVISION OF THE TEXT

March 2008.