

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Multivitamin Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

<u>Active Substances:</u>	<u>Quantity per ml:</u>
Vitamin A Palmitate	15,000I.U
Cholecalciferol (Vitamin D3)	25micrograms
Vitamin E Acetate	20mg
Thiamine Hydrochloride (Vitamin B1)	10mg
Riboflavin Sodium Phosphate (Vitamin B2)	5mg
Pyridoxine Hydrochloride (Vitamin B6)	3mg
Nicotinamide	35mg
Dexpanthenol	25mg
Cyanocobalamin (Vitamin B12)	25micrograms

Excipients:

Chlorocresol (preservative)	1.0mg
Butylated hydroxyanisole (antioxidant)	0.1mg
Butylated hydroxytoluene (antioxidant)	0.1mg

For a full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection

A gold coloured sterile aqueous solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, Pigs, Sheep

4.2 Indications for use, specifying the target species

For the prevention and treatment of vitamin deficiencies in animals, particularly during periods of illness, convalescence and general unthriftiness.

4.3 Contraindications

Do not use in animals known to be hypersensitive to the active substances.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals:

None

Special Precautions to be taken by the Person Administering the Product to Animals:

None known.

4.6 Adverse reactions (frequency and seriousness)

In very rare cases (i.e. less than 1 animal in 10,000 animals) allergic type reactions may occur, and in extreme cases these can result in death.

4.7 Use during pregnancy, lactation or lay

Multivitamin Injection can be safely administered to pregnant and 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

Administer by intramuscular or subcutaneous injection. Avoid the introduction of contamination during use. The injection may be repeated at intervals of 10 – 14 days.

Cattle	20 –30	ml
Calves, sheep and pigs	5 – 10	ml
Weaners and lambs	2 – 5	ml
Piglets up to 9 kg (20 lb)	0.5 – 2	ml

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

Not applicable

4.11 Withdrawal period(s)

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

Edible tissues: Cattle, Pigs, Sheep; 28 days.

Milk: Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic Group; Vitamin B complex including combinations.

ATC Vet Code; QA11E.

Vitamin A is converted to retinol in the eye and is also responsible for the stability of cellular membranes.

Vitamin D3 plays a major role in the regulation of calcium and phosphate plasma concentrations.

Vitamin E functions as an antioxidant and free radical agent particularly for the unsaturated fatty acids in the phospholipids of cell membranes.

Vitamin B1 acts as a co-enzyme in the breakdown of glucose and glycogen.

Vitamin B2 Sodium Phosphate is phosphorylated to form the co-enzymes Riboflavin-5-phosphate and Flavin Adenine Dinucleotide (FAD) which act as hydrogen recipients and donors.

Vitamin B6 is converted to pyridoxal phosphate which functions as a co-enzyme with the transaminases and decarboxylases in the metabolism of proteins and amino acids.

Nicotinamide is converted to the essential co-enzymes Nicotinamide Adenine Dinucleotide (NAD) and Nicotinamide Adenine Dinucleotide Phosphate (NADP).

Pantothenol or pantothenic acid is converted to Co-enzyme A which has a key role in the metabolism of carbohydrates and amino acids and in the synthesis of fatty acids, steroids and acetyl co-enzyme A.

Vitamin B12 is required for the synthesis of nucleic acid components, synthesis of red blood cells and the metabolism of propionate.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chlorocresol
Citric Acid Monohydrate / Sodium Hydroxide Solution
Polysorbate 80
Disodium Edetate
Propylene Glycol
Butylated hydroxyanisole
Butylated hydroxytoluene
Water for Injections

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal 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 25°C. Protect from light.

6.5 Nature and composition of immediate packaging

50 ml and 100 ml type II glass (amber) containers, sealed with nitril rubber bungs 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)

VPA22664/033/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 1991
Date of last renewal: 31 August 2007

10 DATE OF REVISION OF THE TEXT

January 2019