IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) REGULATIONS 2007

(S.I. No. 144 of 2007)

VPA: **10823/017/001**
Case No: 7001831

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies Regulations (S.I. No. 144 of 2007) hereby grants to:

Chem-Pharm

Ballyvaughan, **Co. Clare**, **Ireland**

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:

Multivitamin 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 the said Schedule.

The authorisation, unless previously revoked, shall continue in force from **01/10/2006**.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: From this date of effect, this authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Multivitamin Injection.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substances	
Vitamin A Palmitate	15000 I.U.
Vitamin D3 (Cholecalciferol)	25 micrograms
Vitamin E (Alpha tocopheryl acetate)	20 mg
Vitamin B1 (Thiamine hydrochloride)	10 mg
Vitamin B2 (Riboflavin Sodium Phosphate)	5 mg
Vitamin B6 (Pyridoxine)	3 mg
Nicotinamide	35 mg
Dexpanthenol	25 mg
Vitamin B12 (Cyanocobalamin)	25 micrograms
Excipients	
Chlorocresol (Preservative)	1 mg
Butylated hydroxyanisole	0.1 mg
Butylated hydroxytoluene	0.1 mg

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, Sheep, Pigs.

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 unthriftness.

4.3 Contraindications

None known.

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.

4.6 Adverse reactions (frequency and seriousness)

None known.

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 interaction

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 9kg (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

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

Vitamin D_3 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 B_1 acts as a co-enzyme in the breakdown of glucose and glycogen.

Vitamin B_2 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 B_6 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 B_{12} 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 / Sodium Hydroxide Solution
Polysorbate 80
Disodium Edetate
Propylene Glycol
Butylated hydroxyanisole
Butylated hydroxytoluene
Water for Injections

6.2 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 25^0C.
Protect from light.

6.5 Nature and composition of immediate packaging

100 ml type II glass (amber) containers, sealed with nitryl rubber bungs and aluminium caps.

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

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

7 MARKETING AUTHORISATION HOLDER

Chem-Pharm Ltd
Ballvaughan
Co Clare
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10823/17/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

24/08/2007

10 DATE OF REVISION OF THE TEXT

None.