IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10823/018/001**
Case No: 7002641

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:

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:

VITBPLEX Solution 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 the said Schedule.

The authorisation, unless previously revoked, shall continue in force from **30/09/2006**.

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

VITBPLEX Solution for Injection.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substances	
Thiamine Hydrochloride	35 mg
Riboflavin Sodium Phosphate	0.5 mg
Pyridoxine Hydrochloride	7 mg
Nicotinamide	23 mg
Ascorbic Acid	70 mg

Excipients	
Chlorocresol (preservative)	1 mg

For a full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.
A pale yellow to brown sterile aqueous solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, Sheep, Pigs.

4.2 Indications for use, specifying the target species

For the treatment of cerebrocortical necrosis in cattle and sheep, and for the treatment of Vitamin B deficiencies in cattle, sheep and pigs.

4.3 Contraindications

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

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 Product to Animals

None.

4.6 Adverse reactions (frequency and seriousness)

VitBPlex Injection may occasionally cause local reaction at the site of injection.
This should resolve naturally within a short period of time.

4.7 Use during pregnancy, lactation or lay

This product may be 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 subcutaneous or intramuscular injection. The dose should be repeated daily as required. Avoid the introduction of contamination during use.

Cattle	20 - 30 ml
Calves	5 - 10 ml
Sheep, pigs	5 - 10 ml

If dose volume exceeds 20 ml, it should be divided and injected into two sites.

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

Not applicable

4.11 Withdrawal Period(s)

Edible Tissues and Milk: zero days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Thiamine Hydrochloride (Vitamin B1) acts as a co-enzyme in the breakdown of glucose and glycogen.
Riboflavin Sodium Phosphate (Vitamin B2) is phosphorylated to form the co-enzymes Riboflavin-5-phosphate and Flavin Adenine Dinucleotide (FAD) which act as hydrogen recipients and donors.
Pyridoxine Hydrochloride (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 into the essential co-enzymes Nicotinamide Adenine Dinucleotide (NAD) and Nicotinamide Adenine Dinucleotide Phosphate (NADP).
Vitamin C (Ascorbic Acid) is involved in the conversion of folic acid to tetrahydrofolic acid and the conversion of proline to hydroxyproline which is essential to the formation of collagen.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium Edetate
Propylene Glycol
Chlorocresol
Sodium Hydroxide
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.
Once the vial has been broached, the contents should be used within 28 days.

6.4 Special precautions for storage

Do not store above 25ºC.
Protect from light.

6.5 Nature and composition of immediate packaging

The veterinary medicinal product is packaged in 50 ml and 100 ml amber Type II glass vials, sealed with bromobutyl bungs and aluminium caps.

Not all pack sizes may be marketed.

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.
Ballyvaughan
Co. Clare

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10823/18/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2001 / 30th September 2006