IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10956/007/001**
Case No: 7003024

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:

Ballinskelligs Vet. Products Ltd

Ballinskelligs, **Co. Kerry**, **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:

B.V.P. Copper with Vitamin B 12

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

B.V.P. COPPER WITH VITAMIN B12 INJECTION.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substances	
Copper Methionate	20 mg/ml
Vitamin B12	1 mg/ml
Excipients	
Chlorocresol	2 mg/ml

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

A suspension for injection.
A blue - purple coloured sterile aqueous suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle & Sheep.

4.2 Indications for use, specifying the target species

For the treatment of hypocuprosis in cattle with concurrent anaemia.
For the prevention and treatment of copper and cobalt deficiency in sheep.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.
Not for administration by the intravenous route.

4.4 Special warnings for each target species

The copper status of animals should be checked pre-treatment. This is particularly important in sheep where overdose can lead to haemolytic crisis.

4.5 Special precautions for use

Special precautions for use in animals

Shake the vial vigorously to resuspend the product prior to use.
Inject into a clean site in the neck area by deep intramuscular injection. Avoid injecting into the rump muscles. It is generally advised to avoid injection on wet days as this can generally increase the likelihood of contamination.

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

None.

4.6 Adverse reactions (frequency and seriousness)

The use of parenteral injections can sometimes give rise to toxic reactions as well as allergic type responses with respiratory distress. Such reactions should be treated symptomatically.
Local tissue reaction may occur at the site of injection in cattle, but will be transient and disappear in less than one month.

4.7 Use during pregnancy, lactation or lay

Safe for use during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Administration is by deep intramuscular injection into the neck area.
The dosage and frequency of therapy required depends on the clinical condition of the animal and the copper status, as assessed by blood and liver levels both before and after therapy.
The recommended dosage rate is 20 mg copper and 1 mg Vitamin B12 per 50kg bodyweight.
The following is given as a guide to dosage:

Cattle (Adult)	4-6 ml	Ewes	2 ml
Calves	1-2 ml	Lambs	0.5 ml

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

Overdosage must be avoided. There is no specific antidote.

4.11 Withdrawal Period(s)

Milk: Nil.
Meat: Animals must not be slaughtered for human consumption within 21 days of administration.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

The product is designed for treatment of hypocuprosis in cattle with concurrent anaemia and for prevention and treatment of copper and cobalt deficiency in sheep.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chlorocresol
Water for Injection

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^{o}C.

6.5 Nature and composition of immediate packaging

A 50ml Type II uncoloured glass vial, with nitryl bung and gold coloured seal.

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

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Tairgi Tread-Lia Baile na Sceilge Teo,
(Ballinskelligs Veterinary Products),
Ballinskelligs,
Killarney,
Co. Kerry.
Ireland.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10956/7/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2006

10 DATE OF REVISION OF THE TEXT

15th July 2008