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

To the user:
Accidental injection/self injection may result in severe pain and swelling, particularly if injected into a joint or finger. If you are accidentally injected with this product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examiniation, seek medical advice again.

To the physician:
Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis. Expert, PROMPT, surgical attention may be required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

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 1mg 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 100ml 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 10956/007/002

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1991
Date of last renewal: 30th September 2006

10 DATE OF REVISION OF THE TEXT

July 2014