Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Copper 20mg/ml Suspension for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Copper (as copper methionate) 20 mg

Excipient:
Chlorocresol (as preservative) 1 mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

A sterile blue suspension for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle and Sheep.

4.2 Indications for use, specifying the target species

For the prevention and treatment of copper deficiency in cattle and sheep.

4.3 Contraindications

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

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 re-suspend the solid prior to use.
Inject into a clean site only in the neck area by deep intramuscular injection.
Avoid injection into the rump muscles.
It is generally advised to avoid injection on wet days as this can increase the likelihood of contamination.
The product should not be administered with any other injections.

Special precautions to be taken by the person administering the 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)

Local tissue reaction may occur at the site of injection in cattle, but will be transient and disappear in less than one month.
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.

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.

4.9 Amounts to be administered and administration route

Administration is by deep intramuscular injection only into the neck area.
The stopper may be safely punctured up to 10 times.
When treating groups of animals in one run, use a draw-off needle that has been placed in the vial stopper to avoid excess broaching of the stopper. The draw-off needle should be removed after treatment.
Recommended dosage rate is 20mg copper per 50kg bodyweight in both sheep and cattle.
The dosage and frequency of therapy required depends upon the clinical condition and copper status of the animal as assessed by blood and liver levels both before and after therapy.
The following is given as a guide to dosage:

Lambs: 0.5 ml	Sheep: 2 ml
Calves: 1-2 ml	Adult Cattle: 4-6 ml

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

Do not overdose. There is no specific antidote.

4.11 Withdrawal Period(s)

Milk: Nil.
Meat: Animals intended for human consumption must not be slaughtered until 21 days after the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

The product is designed for prevention and treatment of copper deficiency and clinical conditions associated with copper deficiency. To maintain normal copper levels in lactating dairy cattle.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polysorbate 80
Chlorocresol
Water for Injections

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

Any product remaining 28 days after first opening should be discarded.

6.4 Special precautions for storage

Do not store above 25^{o}C.

Protect from light.

6.5 Nature and composition of immediate packaging

A 100 ml clear glass (Type II Ph Eur) multidose injection vial, with chlorobutyl bung and aluminium seal.

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

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

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10956/005/002

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1991

Date of first renewal: 29th September 2006

10 DATE OF REVISION OF THE TEXT

November 2015