# Summary of Product Characteristics

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Veticop 20mg/ml Suspension for Injection

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

**Active substance**:
Copper (as copper methionate) 20mg

**Excipient**:

Chlorocresol (as preservative) 1mg

For a full list of excipients, see section 6.1

## 3. PHARMACEUTICAL FORM

Suspension for Injection

A sterile blue suspension which upon standing, gradually leaves a clear supernatant.

## 4. CLINICAL PARTICULARS

### 4.1.1 Target Species

Sheep

### 4.2 Indication for use, specifying the target species

For the prevention and treatment of copper deficiency (hypocuprosis) in sheep and for the prevention of swayback in lambs by administering a single injection to the ewe 2.5 months pre-lambing.

### 4.3 Contra-indications

Do not administer intravenously of intramuscularly.
Do not overdose as there is no specific antidote.
Do not administer other forms of copper treatment or supplementation concurrently.

## 4.4 Special warnings for each target species.

The copper status on farms may change from year to year: it is therefore recommended that random samples of serum are periodically checked to see if the deficiency still exists, as sheep are sensitive to copper toxicity.

## 4.5 Special precaution for use

Special precautions for use in animals
Shake the vial vigorously prior to use.

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

None

## 4.6 Adverse reactions (frequency and seriousness)

Some local reactions occur occasionally. These usually subside in time.

## 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

Do not administer with other forms of copper treatment or supplementation.

## 4.9 Amounts to be administered and administration route

The need for therapy should be assessed on serum and liver analysis before treatment. Inject into a clean site subcutaneously in the brisket. The following dosage schedule is given as an average guide: Ewes 2ml, 2.5 months prior to lambing. Shake the vial vigorously to resuspend the solid prior to use,
In keeping with safe practice the animal should be restrained in order to avoid injury to animals or human beings. Use aseptic technique.

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

Do not overdose, as there is no specific antidote
Excess copper accumulates in the liver and can result in a haemolytic crisis leading to death. Suffolk, Texel, Welsh and rare breeds are particularly susceptible.

## 4.11 Withdrawal Period(s)

Ewes meat – 28 days

## 5.0 PHARMACOLOGICAL PROPERTIES:

The product is designed to restore copper levels in cases of deficiency. Copper is an essential element in many enzyme systems.
A primary deficiency results from inadequate intake in certain geographical areas.
A secondary deficiency is associated with excess intake of molybdenum, iron or sulphur. Deficiency in mid-gestation in sheep can result in enzootic ataxia ("swayback") of lambs. Correction by injection of copper is facilitated by use of the Methione salt, which is absorbed slowly and acts as a depot. Excess copper can result in a toxicosis.

## 6.0 PHARMACEUTICAL PARTICULARS:

### 6.1 List of Excipients:

Chlorocresol (Antimicrobial preservative) 1.0mg/ml
Polysorbate 80
Water for Injection

### 6.2 Incompatibilities:

None known

### 6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 30 months.
Shelf life after first opening the immediate packaging: 28 days.

### 6.4 Special precautions for storage:

Do not store above 25$^{o}$C. Protect from light. Avoid extremes of temperature.Following withdrawal of the required dose use the product within 28 days. Discard any unused material.

### 6.5 Nature and contents of immediate packaging:

100ml polypropylene vials with rubber chlorobutyl bung and aluminium overseal.

**6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products, if appropriate:**

Any unused veterinary medicinal product or waste materials derived from such veterinary products should be disposed of in accordance with local requirements.

## 7. MARKETING AUTHORISATION HOLDER

Ballinskelligs Veterinary Products,
Ballinskelligs,
Co. Kerry,
Ireland.

## 8. MARKETING AUTHORISATION NUMBER

Vm 12828/4001

## 9. DATE OF FIRST AUTHORISATION

2 April 1997

## 10. DATE OF REVISION OF THE TEXT

February 2016

Approved: 24 February 2016