

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Copper 20 mg/ml Suspension for Injection for cattle and sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Copper (as copper methionate) 20 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Chlorocresol (as preservative)	1 mg
Polysorbate 80 Chlorocresol	
Water for Injections	

A sterile blue suspension for injection.

3. CLINICAL PARTICULARS

3.1. Target species

Cattle and sheep.

3.2. Indications for use for each target species

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

3.3. Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

Not for intravenous administration.

3.4. Special warnings

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

3.5. Special precautions for use

Special precautions for safe use in the target species:

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 veterinary medicinal product should not be administered with any other injections.

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 veterinary medicinal 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 examination, seek medical advice again.

To the physician:

Even if small amounts have been injected, accidental injection with this veterinary medicinal 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.

Special precautions for the protection of the environment:

Not applicable.

3.6. Adverse reactions (frequency and seriousness)

Cattle and sheep:

Undetermined frequency:	Injection site reaction ¹ Toxic reactions ² Allergic reactions ² Respiratory distress ²
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¹ In cattle, transient and disappear in less than one month.

²The 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.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7. Use during pregnancy, lactation and lay

Pregnancy and lactation:

Can be used during pregnancy and lactation.

3.8. Interaction with other medicinal products and other forms of interaction

None known.

3.9. Administration route and dosage

Deep intramuscular use.

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 20 mg copper per 50 kg 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

3.10. Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Do not overdose. There is no specific antidote.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12. Withdrawal periods

Milk: Zero days.

Meat and offal 21 days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QA12CX

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

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

Shelf life after first opening the immediate packaging: 28 days.

5.3. Special precautions for storage

Do not store above 25 °C.

Protect from light.

5.4. Nature and composition of immediate packaging

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

5.5. Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

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

7. MARKETING AUTHORISATION NUMBER(S)

VPA10956/005/002

8. DATE OF THE FIRST AUTHORISATION

01/10/1991

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

25/08/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product not subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (<https://medicines.health.europa.eu/veterinary>).