IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) REGULATIONS 2007

(S.I. No. 144 of 2007)

VPA: **10277/050/001**
Case No: 7003580

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies Regulations (S.I. No. 144 of 2007) hereby grants to:

Schering Plough Limited

Shire Park, **Welwyn Garden City**, **Hertfordshire AL7 1TW**, **United Kingdom**

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:

Coprin Suspension for Injection

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.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: 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

Coprin Suspension for Injection.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substances

Calcium copper edetate 33.80% w/w

(to give 100 mg copper per syringe)

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Suspension for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle.

4.2 Indications for use, specifying the target species

For the treatment and prevention of copper deficiency.

4.3 Contraindications

Do not administer to sheep of any age. Do not administer to cattle that have received other copper medication or have been fed a copper supplemented diet.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

It is strongly recommended that the existence of copper deficiency should be proved by laboratory methods before this product is first used. Also, as conditions can vary from year to year, the copper status of the herd should be checked periodically to confirm that copper deficiency still exists.

4.6 Adverse reactions (frequency and seriousness)

As with other forms of supplementation, the use of parenteral injections can sometimes give rise to toxic reactions and fatalities have been reported. Also allergic type responses, with respiratory distress, are noted occasionally following the use of Coprin and the signs exhibited can be quite severe in some cases.

It is recommended that any animal showing a marked systemic reaction to Coprin should be treated with high doses of corticosteroid, preferably by the intravenous route. Local reactions in the form of swellings with associated sensitivity may occur following treatment with Coprin. These reactions will subside in a short period of time. Reactions may be more pronounced when the animal is being treated for severe copper deficiency.

4.7 Use during pregnancy, lactation or lay

There are no special precautions recommended.

4.8 Interaction with other medicinal products and other forms of interaction

No other medicinal product should be administered within a 48 hour period before or after Coprin Injection and 'stressful' manipulative procedures should be avoided.

4.9 Amounts to be administered and administration route

For subcutaneous administration only.

Cattle in average or good bodily condition

Under 100 kg bodyweight	-	50 mg (1/2 syringe)
Over 100 kg bodyweight	-	100 mg (1 syringe)

The dose of 50 or 100 mg may be repeated every 4 months as necessary. It may be repeated more frequently if a continuing copper deficiency is demonstrated by blood sampling: a blood test 4 - 6 weeks after each injection is suggested to confirm the need for further treatment.

Cattle in poor health or bodily condition

The dose of 50 mg should not be exceeded at any one time, irrespective of bodyweight. It may be repeated depending on the results of blood testing.

Severely deficient cattle

Adult cattle and growing stock aged one year or more, may receive a dose of 200 mg (2 syringes), provided that a severe deficiency has been confirmed by means of a recent blood test result. In highly deficient areas, this dosage may need to be given more than once during the grazing season. A blood test should be carried out 4 - 6 weeks after each injection to confirm the need for further treatment.

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

Overdosage with any copper preparation may lead to toxicity. It is recommended that any animal showing a marked systemic reaction to Coprin should be treated with high doses of corticosteroid, preferably by the intravenous route.

4.11 Withdrawal Period(s)

Animals must not be slaughtered for human consumption during treatment.

Animals for human consumption must not be slaughtered until after 7 days from the last treatment.

No withholding period is necessary for milk from treated cattle.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Summary Presentation of the Active Ingredient

Calcium copper edetate is a copper compound for injection in a water miscible base providing a supplement of copper.

5.1 Pharmacodynamic properties

Copper is an essential trace element primarily because there are several copper dependent enzymes involved with iron metabolism, elastin and collagen formation, melanin production and integrity of the central nervous system. It is, for example, an integral part of the co-factor cytochrome oxidase, which is concerned with the oxidation processes and electron transfer in tissues. Loss of cytochrome oxidase impairs phospholipid synthesis, which may explain the reduced formation of myelin seen in the central nervous system (CNS) of swayback lambs.

Copper is also a component of the enzyme lysyl oxidase which plays a part in elastin and collagen synthesis. These compounds give strength and elasticity to connective tissue and cartilage; thus copper deficiency can lead to skeletal defects, abnormal gait and fragility of blood vessels.

Copper is also found in ceruloplasmin (ferroxidase I), an oxidative enzyme found in blood plasma. It contains 80 - 90% of the plasma copper, and is involved in releasing iron into plasma from stores, thus facilitating erythropoiesis.

Copper is also found in erythrocytes, mainly as erythrocuperin, which acts as an enzyme, superoxide dimutase. The liver stores release copper as necessary, for incorporation into enzyme systems.

5.2 Pharmacokinetic properties

Copper is rapidly depleted from the site of administration, becoming bound to plasma albumin in the bloodstream. Peak serum concentrations occur about 4 hours after treatment as the copper is transported to the liver, the main storage organ for this element. Here copper is chiefly found in the parenchyma with only small amounts in the recticuloendothelial cells. Though most copper is stored in the liver, small amounts are immediately released for metabolic purposes, and some excreted. The main excretion pathway is via the bile and hence the faeces, though urine and milk contain low levels of copper. Some re-absorption may take place in the intestine.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid Paraffin Light
Sorbitan Stearate
Polysorbate 60
Formaldehyde (35 per cent) solution
Sodium Metabisulphite
Water for Injection

6.2 Incompatibilities

None known.

6.3 Shelf-life

24 months.
Discard part-used syringes. For single-use only.

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 smooth, blue, homogenous paste like suspension for injection supplied in a white 2 g polypropylene syringe (white polypropylene plunger, synthetic rubber washer piston seal, push-on luer cap).

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

Schering Plough Ltd.
Shire Park
Welwyn Garden City
Hertfordshire
AL7 1TW
England

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10277/50/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2004

10 DATE OF REVISION OF THE TEXT

9th August 2005

17th July 2007