IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007

(S.I. No. 786 of 2007)

VPA: **10987/032/001**
Case No: 7005993

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

Chanelle Pharmaceuticals Manufacturing Limited

Loughrea, **Co. Galway**, **Ireland**

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:

Cobalt Super Oral solution 2.1 mg/ml

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.

The authorisation, unless previously revoked, shall continue in force from **01/10/2009**.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: From this date of effect, 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

Cobalt Super Oral Solution 2.1mg/ml

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Cobalt (as cobalt sulphate heptahydrate) 2.1 mg/ml

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Oral solution

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, Calves, Sheep and Lambs

4.2 Indications for use, specifying the target species

Cobalt Super is intended for the prevention and treatment of Cobalt deficiency (pining) and associated signs such as scouring and decreased reproductive performance.

4.3 Contraindications

None known.

4.4 Special warnings for each target species

The product is not recommended for use in calves and lambs under 8 weeks of age.

4.5 Special precautions for use

Special precaution(s) for use in animals

This product should only be used where Cobalt deficiency is known to exist. Farmers are advised to have their animals regularly checked for deficiency.

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

At sheep dipping, dose before dipping to avoid handling sheep.

4.6 Adverse reactions (frequency and seriousness)

None known at the correct dosage.

4.7 Use during pregnancy, lactation or lay

There are no precautions 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

For oral administration only.
Shake well before use.

The product is indicated in the prevention and treatment of 'Pine' also known as 'Vinquish' or 'Galra thrua'. Affected Sheep and Lambs lose their appetite becoming thin, unthrifty and weak. Scouring is present which does not respond to dosing for worms. The eyes are watery and ears droop and the sheep walks with difficulty. Cobalt deficiency may contribute to other nutritional disorders such as Twin Lamb Disease.

Ideally, Cobalt should be given as frequently as possible because it is not effectively recycled and no effective stores exist in the body. However, periodic drenching with oral cobalt is effective when adequate doses are given every 14 days (2 weeks) or every 21 days (3 weeks).

Cattle

	Dosing Interval Two weeks	Dosing Interval Three weeks
Calves	30 ml	45 ml
Growing Cattle	50 ml	75 ml
Lactating Cattle	70 ml	105 ml

Sheep

	Dosing Interval Two weeks	Dosing Interval Three weeks
Lambed Ewe	15 ml	22.5 ml
Dry Ewes	15 ml	22.5 ml
Lambs	10 ml	15.0 ml

For Pining and associated signs such as scouring and decreased reproductive performance, the two week dose should be given every second day until 4 doses have been given.

Cobalt Super can be given in a little water.

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

Cobalt is relatively nontoxic, and toxicity is not recognised under natural conditions. Overdoses may result in depressed appetite, weight loss and anaemia, which is strangely analogous to the description of deficiency.

4.11 Withdrawal Period(s)

Meat: 0 days. Animals intended for human consumption may be slaughtered following treatment.
Milk: 0 days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Nutrients.

ATCvet code: QV06D

5.1 Pharmacodynamic properties

Mineral deficiencies can occur from inadequate ingestion, absorption and utilisation of minerals or from an increased requirement, destruction or increased excretion of minerals, or from a combination of these factors. Cobalt is an essential mineral in sheep and cattle diets. Cobalt Super, an oral drench for cattle and sheep, contains this mineral in its sulphate salt form.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf-life

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

6.4 Special precautions for storage

Do not store above 25^{o}C

6.5 Nature and composition of immediate packaging

High density polythene container and closure.

Pack sizes: 500 ml, 1 litre, 2.5 litre and 5 litre.

Not all pack sizes may be marketed.

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

Chanelle Pharmaceutical Manufacturing Ltd.
Loughrea
Co. Galway

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10987/032/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2004

10 DATE OF REVISION OF THE TEXT