SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cosecure Cattle Bolus Continuous Release Intraruminal

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100g bolus contains the following active substances:

Copper:	13.4g
Cobalt:	0.5g
Selenium, as sodium selenate	0.3g

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Continuous release intraruminal device.

A cylindrical, blue glass continual release intraruminal device approximately 82mm x 24mm and weighing approximately 100g, referred to throughout the text as a bolus.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle (over 2 months and weighing at least 100 kg BW)

4.2 Indications for use, specifying the target species

For prevention and treatment of copper and selenium deficiencies and for improvement of cobalt supply.

4.3 Contraindications

Do not administer to non-ruminating calves or to animals weighing less than 100kg body weight. Do not administer to sheep.

See also Section 4.5, Special Precautions for Use

4.4 Special warnings for each target species

The product is not intended for treatment of acute clinical conditions such as nutritional muscular dystrophy.

4.5 Special precautions for use

(i) Special precautions for use in animals

Prior to supplementation with any form of copper or selenium, it should be demonstrated that there is a need for extra trace elements to be given to the animals.

Additional copper should not be administered orally or by injection, or selenium by injection, within six months after administration of the product to cattle at pasture or within 4.5 months in cattle where the diet is supplemented with concentrates unless subjected to a risk/benefit analysis performed by a responsible veterinarian in each case.

Do not administer any aids to alter dissolution of the bolus.

The boluses are sensitive to sudden temperature changes such as those that may occur when very cold boluses are swallowed by an animal. Therefore it is important that the bolus is at room temperature (15 - 20°C) prior to administration to prevent the development of fine cracks that may change the activity of the bolus.

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

In order to minimise the risk of contact allergy, wear gloves when handling this product.

4.6 Adverse reactions (frequency and seriousness)

None known

4.7 Use during pregnancy, lactation or lay

The product may be administered to pregnant and lactating animals

4.8 Interaction with other medicinal products and other forms of interaction

None known

4.9 Amounts to be administered and administration route

Ruminating cattle over two months of age and weighing over 100 kg body weight: 2 boluses.

Administer orally using an oesophageal balling-gun, which delivers the bolus directly into the top of the gullet. Great care should be taken not to cause any injury by rough handling or by placing the gun too far inside the throat of the animal. Ensure that each animal has swallowed the boluses by holding the mouth closed and observing the animal for a short time after dosing. Gentle massage of the throat may facilitate swallowing of the boluses.

The boluses should normally be administered just before turnout, but administration may be carried out at any time, e.g. administer to dairy cows at drying off or at calving or 30 days post-calving or at artificial insemination.

The boluses are sensitive to sudden temperature changes such as those that may occur when very cold boluses are swallowed by an animal. Therefore, it is important that the bolus is at room temperature (15 - 20°C) prior to administration to prevent the development of fine cracks that may change the activity of the bolus.

To minimise the risk of regurgitation, avoid rough handling of animals after dosing.

Do not administer the recommended dosage to animals more frequently than once every 4.5 months to animals receiving concentrates or every 6 months to cattle at pasture.

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

No adverse effects have been observed in cattle administered three times the recommended dosage over a two-day period. Clinical signs of copper toxicity, which normally will only occur in cases of severe copper overdosage include jaundice, malaise, an acute drop in mild yield and, later, haemoglobinuria. Signs of selenium toxicity include CNS changes, muscle weakness, vomiting, anorexia, depression, incoordination and, later, respiratory problems. In these circumstances, intravenous administration of copper and/or selenium chelating agents such as ammonium tetrathiomolybdate or EDTA (ethylendiaminetetraacetic acid) is recommended.

Ammonium tetrathiomolybdate (ATTP) is often quoted in veterinary literature as an antidote to copper poisoning. ATTP is not an authorised veterinary medicine. Any pharmacologically active substances used in a veterinary medicinal product administered to a food-producing animal under the cascade must be listed in Annex I, II or III to Council Regulation (EEC) No 2377/90. As ATTP does not appear in any of these Annexes it should not be administered to an animal intended for food production.

4.11 Withdrawal period(s)

Cattle: Meat zero days; milk zero hours.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: selenium combinations

ATCvet code: QA12CE99

5.1 Pharmacodynamic properties

The active substances are the essential trace elements copper, cobalt and selenium. The boluses are designed to dissolve slowly throughout the grazing season (up to 6 months), releasing copper, cobalt and selenium.

Copper is an integral part of several enzymes with oxidase function e.g. caeruloplasmin, monoamine oxidase, cytochrome oxidase, tyrosinase, lysyl oxidase, cytochrome C and superoxide dismutase. Thus copper is essential for a variety of body functions including growth. In addition, extra copper supplementation is essential in cases of infertility due to the formation of thiomolybdates with molybdenum.

Cobalt is an integral part in Vitamin B12 (cyanocobalamin), which is important for several metabolic functions. This vitamin is synthesised by micro-organisms in the rumen and is absorbed from there into the systemic circulation. Vitamin B 12 acts as a co-enzyme in several metabolic pathways and in ruminants its main role is in the metabolism of propionate, which is required for synthesis of glucose via succinate in the liver.

Selenium is an integral part in the glutathione peroxidase (GSHPx) enzymes, which are involved in the protection from oxidant stress. These enzymes have a synergistic role with vitamin E and other antioxidants in removing toxic peroxides from tissue and preventing oxidative damage to membranes. Selenium is required in the thyroid gland for the conversion of T4 to T3, the active thyroxine molecule as selenium is required in the iodothyronine deiodinase enzymes.

5.2 Pharmacokinetic particulars

Following oral administration the boluses lodge in the reticulum where they dissolve slowly over a period of approximately four and one half to six months. The ultimate breakdown products are copper, cobalt and selenium in ionic form. The boluses provide a source of these trace elements at levels compatible with the animals´ daily requirements.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Phosphorus(V)-oxide

Sodium oxide

Magnesium oxide

Other oxides

6.2 Incompatibilities

None known.

6.3 Shelf life

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

Shelf-life after first opening the immediate packaging: 6 months.

6.4. Special precautions for storage

Store in a dry place. Do not freeze. Protect from frost

Once the package has been opened, store unused boluses in the plastic tray in the original packaging in an airtight container.

6.5 Nature and composition of immediate packaging

Five PCV trays, each containing four boluses and vacuum heat sealed in a polyester/aluminium foil laminate pouch, contained in a printed carton.

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

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

7. MARKETING AUTHORISATION HOLDER

Telsol Limited

23/24 Colomendy Industrial Estate

Denbigh

Denbighshire

LL16 5TA

8. MARKETING AUTHORISATION NUMBER

Vm 18584/4000

9. DATE OF RENEWAL OF THE AUTHORISATION

27 April 2010

10 DATE OF REVISION OF THE TEXT

January 2011

PROHIBITION OF SALE, SUPPLY AND/OR USE

None