1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cosecure Cattle Bolus Continuous Release Intraruminal Device

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 g bolus contains:

Active substances:

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

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Phosphorus (V)-oxide	
Sodium oxide	
Magnesium oxide	
Other oxides	

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

3. CLINICAL INFORMATION

3.1 Target species

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

3.2 Indications for use for each target species

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

3.3 Contraindications

Do not administer to non-ruminating calves or to animals weighing less than 100 kg body weight. Do not administer to sheep.
See also Section 3.5, Special precautions for use.
Do not use in cases of hypersensitivity to the active substances, or to any of the excipients.

3.4 Special warnings

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

3.5 Special precautions for use

Special precautions for safe use in the target species:
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 veterinary medicinal 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 ºC) prior to administration to prevent the development of fine cracks that may change the activity of the bolus.

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 veterinary medicinal product.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

None known.

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 or 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 routes and dosage

Intraruminal use.

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 bolus 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 ºC) 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.

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

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 including jaundice, malaise, an acute drop in milk 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 (ethylenediaminetetraacetic 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 allowed substances in accordance with Regulation (EU) No 470/2009 i.e. listed in Table 1 of the Annex to Regulation (EU) No 37/2010. As ATTP does not appear in this table, it should not be administered to an animal intended for food production.

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

Cattle:
Meat and offal: Zero days.
Milk: Zero hours.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code : QA12CE99

4.2 Pharmacodynamics

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 oxide, 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 thiomolybdate 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 B12 acts as a co-enzyme in several metabolic pathways and in ruminants its main role is in the metabolism of propionate, which is require 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.

4.3 Pharmacokinetics

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.

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: 6 months.

5.3 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.

5.4 Nature and composition of immediate packaging

R.PET trays, each containing four boluses and vacuum heat sealed in a polyester/aluminium foil laminate pouch.

Pack size:
Carton box containing 20 boluses.

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

Bimeda Animal Health Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA22033/054/001

8. DATE OF FIRST AUTHORISATION

27/04/2005

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

02/05/2025

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).