

COSECURE

Continuous Release Intraruminal Device

CATTLE BOLUS

DATA SHEET



INDICATIONS

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

EACH 100G BOLUS CONTAINS:

13.4 grams copper

0.3 grams selenium as sodium selenate

0.5 grams cobalt

BENEFITS

- Unique soluble glass formulation ensures that trace elements are delivered at a controlled and constant rate, compatible with the animal's daily requirements.
- Contains ionic copper; a unique, rumen-available form of copper
- Contains ionic cobalt; a unique, rumen-available form of cobalt
- Provides copper, cobalt and selenium for up to six months
- Registered medicine (POM-VPS medicine with proven efficacy)

| LIST No | UNIT PACKAGE |
|---------|--------------|
| 1COS006 | 20 Boluses |

See reverse for Full Product Detail and Usage Instructions



Cattle Bolus COSECURE™

Continuous Release Intraruminal Device



NAME OF THE VETERINARY MEDICINAL PRODUCT

Cosecure Cattle Bolus Continuous Release Intraruminal Device

COMPOSITION

Each 100 g bolus contains:

Active ingredients:

| | |
|------------------------------|--------|
| 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.

PACKAGE SIZE

20 boluses (10 doses).

TARGET SPECIES

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

INDICATIONS FOR USE

Indications for use

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

CONTRAINDICATIONS

Contraindications

Do not administer to non-ruminating calves or to animals weighing less than 100 kg body weight. Do not administer to sheep. Do not use in cases of hypersensitivity to the active substance(s), or to any of the excipients.

SPECIAL WARNINGS

Special warnings

Special warnings:

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

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 6 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°C) 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.

Pregnancy and lactation:

Can be used during pregnancy and lactation.

Interactions with other medicinal products and other forms of interaction:

None known.

Overdose:

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 overdose include 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 Annex it should not be administered to an animal intended for food production.

Special restrictions for use and special conditions for use:
Not applicable.

Major incompatibilities:
None known.

ADVERSE EVENTS

Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder <or the local representative of the marketing authorisation holder> using the contact details on this carton, or via your national reporting system at: Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine> e-mail: adverse.events@vmd.gov.uk

DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

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.

ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

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 can be carried out at any time, e.g. administer to dairy cows at drying off or at calving to 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 minimize 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 animals at pasture.

WITHDRAWAL PERIODS

Withdrawal periods

Cattle:

Meat and offal: Zero days.

Milk: Zero hours.

SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.

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 and use within 6 months.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton after Exp. The expiry date refers to the last day of that month.

SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

Medicines should not be disposed of via wastewater.

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

MARKETING AUTHORISATION NUMBERS AND PACK SIZES

GB: Vm 18584/5000

NI: Vm 50146/3008

Pack sizes

Carton box containing 20 boluses.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

CONTACT DETAILS

Marketing authorisation holder Northern Ireland:

Bimeda Animal Health Limited

Unit 2/3/4 Airton Close

Tallaght

Dublin 24

Ireland

Marketing Authorisation Holder Great Britain

Telsol Ltd

23-24 Colomendy Industrial Estate

Denbigh

Denbighshire, Wales

LL16 5TA

United Kingdom

Local representative and contact details to report suspected adverse reactions:

Cross Vetpharm Group UK Limited (Trading as Bimeda)

Unit 2, Bryn Cefni Industrial Park

Llangefni

LL77 7XA

United Kingdom

Tel: 01248 725 400

OTHER INFORMATION

Other information

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 B12 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 T3 to T4, the active thyroxine molecule as selenium is required in the iodothyronine deiodinase enzymes.

POM-VPS

FOR ANIMAL TREATMENT ONLY

EXPIRY DATE

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

TAKE TIME



OBSERVE LABEL
DIRECTIONS

www.bimeda.ie
www.bimeda.co.uk

cosecureboluses.com

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