

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

The outer package is a carton containing five polyester/polyethylene/aluminium/ polyester heat-sealed laminate pouches, each containing four boluses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cosecure Cattle Bolus Continuous Release Intraruminal Device

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 100g bolus contains the following active substances: Copper 13.4g, Cobalt 0.5g, Selenium, as sodium selenate 0.3g

3. PHARMACEUTICAL FORM

A cylindrical, blue glass continual release intraruminal device approximately 82mm x 24mm and weighing approximately 100g

4. PACKAGE SIZE

Quantity: 20 boluses (10 doses)

5. TARGET SPECIES

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

6. INDICATION(S)

Prevention and treatment of copper and selenium deficiencies and improvement of cobalt supply.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Take care to read the instructions carefully before administering the boluses Administer orally using a 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. Gentle massage of the throat may facilitate swallowing of the boluses. To minimise the risk of regurgitation, avoid rough handling of the animals.
Following administration, the boluses lodge in the reticulum where they dissolve over a period of approximately 4.5 to 6 months. The breakdown products are copper, cobalt and selenium in ionic form. The boluses provide these elements

at levels compatible with the animal's daily requirements. The boluses should normally be administered just before turnout, but can be given at any time, e.g. to dairy cows at drying off or at calving to 30 days post-calving or at artificial insemination.

Boluses are sensitive to sudden temperature changes such as may occur when very cold boluses are swallowed by an animal. 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.

8. WITHDRAWAL PERIOD

Withdrawal period: meat and offal; zero days; milk: zero hours

9. SPECIAL WARNING(S), IF NECESSARY

Protection of operators: to minimise the risk of contact allergy, wear gloves when handling this product.

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

Do not administer to sheep.

Do not administer any aids to alter dissolution of the bolus

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

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

Prior to any form of supplementation with 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 product to cattle at pasture or within 4.5 months to cattle where the diet is supplemented with concentrates unless subjected to a risk/benefit analysis performed by a responsible veterinarian.

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, acute drop yield and, later, haemoglobinuria.

Signs of selenium toxicity include CNS changes, muscle weakness, vomiting, anorexia, depression, incoordination and, later, respiratory problems. In these circumstances, administration of copper and/or selenium chelating agents such as ammonium tetrathiomolybdate or EDTA (ethylenediaminetetraacetic acid) is recommended.

10. EXPIRY DATE

Expiry date:

11. SPECIAL STORAGE CONDITIONS

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
When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this carton, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only
To be supplied only on veterinary prescription

14. THE WORDS “KEEP OUT OF THE REACH AND SIGHT OF CHILDREN”

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Marketing authorisation holder:

UK: Telsol Limited, 23/24 Colomendy Industrial Estate, Denbigh, Denbighshire LL16 5TA

Manufacturer responsible for batch release:

Telsol Limited, 23/24 Colomendy Industrial Estate, Denbigh, Denbighshire LL16 5TA

Bimeda Animal Health Ltd. Unit 2/3/4 Airton Close, Tallaght, Dublin 24, Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 18584/4000

17. MANUFACTURER’S BATCH NUMBER

Batch Number:

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

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

The immediate package is a polyester/polyethylene/aluminium/ polyester heat-sealed laminate pouches containing four boluses

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2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 100g bolus contains the following active substances: Copper 13.4g, Cobalt 0.5g, Selenium, as sodium selenate 0.3g

3. PHARMACEUTICAL FORM

A cylindrical, blue glass continual release intraruminal device approximately 82mm x 24mm and weighing approximately 100g

4. PACKAGE SIZE

4 x 100g boluses (2 doses)

5. TARGET SPECIES

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

6. INDICATION(S)

Prevention and treatment of copper and selenium deficiencies and improvement of cobalt supply.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Take care to read the instructions carefully before administering the boluses Administer orally using a 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. Gentle massage of the throat may facilitate swallowing of the boluses. To minimise the risk of regurgitation, avoid rough handling of the animals.

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

Boluses are sensitive to sudden temperature changes such as may occur when very cold boluses are swallowed by an animal. It is important that the bolus is at room temperature (15 - 20°C) prior to administration.

8. WITHDRAWAL PERIOD

Withdrawal period: meat and offal; zero days; milk: zero hours

9. SPECIAL WARNING(S), IF NECESSARY

Protection of operators: to minimise the risk of contact allergy, wear gloves when handling this product.

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

Do not administer to sheep.

Do not administer any aids to alter dissolution of the bolus

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

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

Prior to any form of supplementation with 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 product to cattle at pasture or within 4.5 months to cattle where the diet is supplemented with concentrates unless subjected to a risk/benefit analysis performed by a responsible veterinarian.

In the event of suspected overdosage, see carton.

10. EXPIRY DATE

Expiry date:

Once opened, use by:

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

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14. THE WORDS “KEEP OUT OF THE REACH AND SIGHT OF CHILDREN”

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15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Telsol Limited, 23/24 Colomendy Industrial Estate, Denbigh, Denbighshire LL16
5TA

16. MARKETING AUTHORISATION NUMBER(S)

Vm 18584/4000

17. MANUFACTURER’S BATCH NUMBER

Batch Number:

B. PACKAGE LEAFLET

No package leaflet is used

Approved: 17/02/21

A handwritten signature in black ink, appearing to read "D. Austin", with a horizontal line extending to the right.