

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RUMBUL RUMEN BULLET 40g CONTINUOUS RELEASE INTRARUMINAL DEVICE, CATTLE.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Bullets composed of an alloy comprising w/w	
Magnesium	86%
Aluminium	12%
Copper weighted with iron shot	2%
Each bolus contains 40g of Magnesium	

3. PHARMACEUTICAL FORM

Continuous release intraruminal device.

4. PACKAGE SIZE

10 cattle bullets (5 doses).

5. TARGET SPECIES

Cattle.

6. INDICATION(S)

An aid to the prevention of hypomagnesaemia in cattle.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration only. Animals should be observed for a few minutes after administration to ensure that bullets are not regurgitated.

FOR FULL INSTRUCTIONS SEE ENCLOSED LEAFLET.

8. WITHDRAWAL PERIOD

Meat and Milk withdrawal Period - Zero days/hours.

(Included in package leaflet not on immediate packaging)

9. SPECIAL WARNING(S), IF NECESSARY

Contra-indications, Warnings etc.

Not to be used in cattle weighing less than 300kg.

FOR FULL INSTRUCTIONS SEE ENCLOSED LEAFLET.

10. EXPIRY DATE

EXP: MM/YYYY

(Printed on side if immediate packaging – 10 years from date of manufacture)

11. SPECIAL STORAGE CONDITIONS

Store in the original package.

Keep the package tightly sealed.

Store in a dry place.

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

Dispose of empty packaging and any remaining product in the farm refuse. Used containers should not be recycled.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only.

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

Keep out of reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Agrimin Ltd, Arlanda Way, Humberside Airport, Kirmington, North Lincolnshire, DN39 6YH. UK

16. MARKETING AUTHORISATION NUMBER(S)

Vm 04261/4003.

17. MANUFACTURER’S BATCH NUMBER

BN: XXXX

(Printed on side if immediate packaging)

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS**

Not applicable.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Not applicable.

PARTICULARS TO APPEAR ON THE IMMEDIATE DILUENT LABEL

Not applicable.

PACKAGE LEAFLET FOR:

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Agrimin Limited

Arlanda Way, Humberside Airport, Kirmington,
North Lincolnshire, DN39 6YH. UK

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

RUMBUL RUMEN CATTLE BULLET – 40g continuous release intraruminal device, Cattle.

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Rumbul Rumen Cattle Bullets are moulded metal cylinders of a magnesium/aluminium/copper alloy (86, 12 and 2% respectively) weighted with iron shot. The cattle bullets contain 40g of magnesium and measure 2.4cms diameter x 7.6cms length. After swallowing they lie in the reticulum or at the base of the rumen and break down by electrolytic action (which prevents the formation of insoluble deposits), releasing magnesium throughout their active life (four weeks). The iron shot is eliminated in the faeces of the animal as small discrete particles.

4. INDICATION(S)

Rumbul Rumen Cattle Bullets are indicated as an aid to the prevention of hypomagnesaemia in dairy cattle of at least 300kg bodyweight during the high risk period associated with the grazing of rapidly growing spring grass. They are not currently recommended for the prevention of the condition at other times of the year, for other types of cattle, or for animals receiving more than minimal quantities of hay, silage and concentrates since the feeding of these can affect the rate of bullet breakdown.

In cases of doubt a farmer should seek the advice of his veterinary surgeon.

5. CONTRAINDICATIONS

Rumbul Rumen Cattle Bullets are particularly recommended for adult dairy cattle when grazing rapidly growing grass in the spring when there is a well defined period

of high risk. It is difficult to establish experimentally their effect at other times of the year when clinical tetany may occur unexpectedly.

Rumbul Rumen Cattle Bullets may occasionally be regurgitated. This may happen very shortly after being administered if they have not been completely swallowed. The bullet may more readily reach the reticulum or base of the rumen if it is not given immediately after hay or silage has been given. Animals should be observed carefully for a few minutes after administration. Towards the end of their useful life (when bullets become shorter and of a greatly reduced diameter) there is a small chance that regurgitation may occur. If it is noticed that an individual animal has regurgitated a bullet, treatment should be repeated.

Rumbul Rumen Cattle Bullets do not necessarily restore blood magnesium concentration to accepted normal levels. In the vast majority of situations good control of hypomagnesaemic tetany is obtained. However, because of the varying complexity of factors involved in the condition as it occurs in different situations there may be a very small proportion of animals which do not respond to the treatment. Rumbul Rumen Cattle Bullets cannot be expected to correct chronic hypomagnesaemia which may follow a long period of under-nutrition.

In areas where there is no known copper deficiency, no additional supplement of copper should be given to cattle which have been administered Rumbul Rumen Cattle Bullets, for the active life of the bullets (four weeks).

6. ADVERSE REACTIONS

(None known)

7. TARGET SPECIES

Cattle.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dosage

Two Rumbul Rumen Cattle Bullets should be given to each animal two/three days before the expected period of risk, e.g. before transfer from indoors to grass in the spring. If necessary, dosage should be repeated after four weeks.

Administration

Administer orally by using the specially designed bulleting gun.

9. ADVICE ON CORRECT ADMINISTRATION



Load the gun by inserting the bullet into the open end. Open the animal's mouth and the gun should then be introduced carefully and gently, until the bullet is in the region of the back of the tongue. Severe pressure on the tongue should be avoided.



Depression of the plunger (fig 3) will deliver the bullet on the rear part of the tongue, thereby initiating a swallowing action. The gun should then be carefully withdrawn from the mouth. (fig 4).

A second bullet should then be administered following the same procedure. Observe each animal for a short time after dosing to ensure both bullets have been swallowed.

Restraint of cattle is best provided by means of a cattle crush and the head and neck should be kept as straight as possible.

10. WITHDRAWAL PERIOD(S)

Meat and Milk withdrawal Period - Zero days/hours.

11. SPECIAL STORAGE PRECAUTIONS

Store in the original package.

Keep the package tightly sealed.

Store in a dry place.

12. SPECIAL WARNING(S)

For Animal treatment only.

Keep out of reach of children.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of empty packaging and any remaining product in the farm refuse. Used containers should not be recycled.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Legal Category

POM - VPS To be supplied only on veterinary prescription

Marketing authorisation number: VM 04261/4003

**MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO
PACKAGE LEAFLET, E.g. Concertina Labels.**

Not applicable.

Approved: 16/06/2017

A handwritten signature in black ink, appearing to read 'J. Long', positioned below the approval date.