

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RUMBUL RUMEN BULLET 15g CONTINUOUS RELEASE INTRARUMINAL DEVICE, SHEEP/CALVES.

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 15g of Magnesium	

3. PHARMACEUTICAL FORM

Continuous release intraruminal device.

4. PACKAGE SIZE

20 SHEEP/CALF BULLETS (20 SHEEP/10 CALF DOSES).

5. TARGET SPECIES

Sheep/calves.

6. INDICATION(S)

An aid to the prevention of hypomagnesaemia in sheep and calves.

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

Not to be used in sheep weighing less than 30kg.

Not to be used in calves weighing less than 50kg.

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 04261/4004

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

Agrimis Limited

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

RUMBUL RUMEN SHEEP/CALVES BULLET - 15g continuous release intraruminal device, Sheep/calves.

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

Rumbul Rumen Sheep/Calves Bullets are moulded metal cylinders of a magnesium/aluminium/copper alloy (86, 12 and 2% respectively) weighted with iron shot. The sheep bullets contain 15g of magnesium and measure 1.9cms diameter x 4.6cms 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 (three weeks).

4. INDICATION(S)

Sheep

Rumbul Rumen Sheep/Calves Bullets are indicated as an aid in the prevention of hypomagesaemia in sheep, of at least 30kg bodyweight, during the high risk period associated with early spring grazing after lambing. Trials have been confined to animals on spring grass.

Calves

Rumbul Rumen Sheep/Calves Bullets are indicated as an aid to the prevention of hypomagesaemia in suckling calves, of at least 50kg bodyweight, where the diet is predominantly milk.

5. CONTRAINDICATIONS

The average life of the bullet in the reticulum or rumen has been shown to be approximately 3 weeks. There may be some variation in the rate of breakdown depending on diet. The incidence of regurgitation of bullets is very low and usually occurs (if at all) towards the end of the active life of the bullet. Rumbul Rumen Sheep/Calves 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 Sheep/Calves 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 sheep or calves which have been administered Rumbul Rumen Sheep/Calves Bullets, for the active life of the bullets (three weeks).

6. ADVERSE REACTIONS

(None known)

7. TARGET SPECIES

Sheep/calves.

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

Dosage

Sheep

One Rumbul Rumen Sheep/Calves Bullet should be given to each animal two days before the expected period of risk, e.g. after lambing or transfer to new grazing. If necessary, dosage should be repeated after three weeks.

Only to be given to Sheep of at least 30kg bodyweight.

Calves

Two Rumbul Rumen Sheep/Calves Bullets should be given to each animal. One treatment should prevent a serious reduction in blood magnesium concentration for at least three weeks; thereafter, dosage should be repeated if the calf is still receiving a predominantly milk diet.

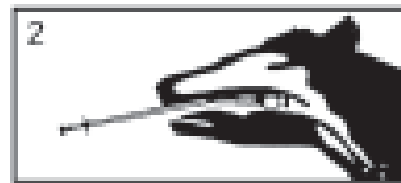
Only to be given to calves of at least 50kg bodyweight.

Administration

Administer orally by using the specially designed bulleting gun. Whilst one man can accomplish the entire operation on his own, two operators constitute a better working arrangement.

The animal is restrained by one man standing astride its shoulders and holding its head, whilst the other man is in charge of the actual administration of the bullet. The head should not be held in too high a position as this interferes with swallowing. The curvature of the gun is designed to facilitate the placing of the bullet on the back of the tongue. It is essential that the gun is maintained in an upright plane in the mid-line of the mouth throughout the operation.

9. ADVICE ON CORRECT ADMINISTRATION



Load the gun by inserting the bullet in 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 to the rear part of the tongue, thereby initiating a swallowing action. The gun should then be carefully withdrawn from the mouth (fig. 4) (For calves only - a second bullet should then be administered following the same procedure).

Observe each animal for a short time after dosing to ensure the bullet(s) has (have) been swallowed.

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>

POM - VPS To be supplied only on veterinary prescription

Marketing authorisation number: VM 04261/4004

**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.