SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rumbul Rumen Bullet 40g continuous release intraruminal device, cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each bullet has a mass of 100g, comprising 46.53g (Mg-Al-Cu) alloy and 53.47g iron shot (ratio 47:53)

Active Ingredient:

Magnesium (in Mg-Al-Cu alloy)	40g/bolus

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Continuous release intraruminal device

Solid preparation of moulded magnesium alloy in bolus form.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle

4.2 Indications for use, specifying the target species

As an aid in 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.

4.3 Contra-indications

Not to be used in cattle weighing less than 300kg

4.4 Special warnings for each target species

Rumbul 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 of silage has been given. Animals should be observed carefully for a few minutes after administration. Towards the end of their useful life (when the bullets become shorter and of considerably 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.

4.5 Special precautions for use

i. Special precautions for use in animals

See 4.9 below for special precautions during administration.

ii. Special precautions to be taken by the person administering the veterinary medicinal product to the animals

There are no special precautions to be taken by person administering Rumbul cattle bullets.

4.6 Adverse reactions (frequency and seriousness)

None known

4.7 Use during pregnancy and lactation

There are no restrictions on the use of the product during pregnancy and lactation

4.8 Interaction with other medicinal products and other forms of interaction

None known

4.9 Amounts to be administered and administration route

Two Rumbul Cattle Bullets should be given to each animal 2/3 days before the expected period of risk, e.g. before turn-out onto rapidly growing spring grass. If necessary dosing should be repeated after 4 weeks.

Administration orally by using the specially designed bulleting gun.
Load the gun by inserting the bullet into the open end, ensuring that the bullet is pressed into the metal cup and held firmly by the rubber head.

The gun should then be passed carefully and gently into the animal's mouth until the rubber head is in the region of the back of the tongue. Severe pressure on the tongue should be avoided. Depression of the plunger will effect delivery of the bullet onto the rear part of the tongue thereby initiating a swallowing action. The gun should then be carefully withdrawn, taking care during removal to maintain its central position in the mouth.

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.

Note 1. It is desirable when administering the bullet that the head and neck are extended in a straight line in front of the animal. Once the bullet has been introduced on to the back of the tongue by means of the gun, its further progress will depend upon the reflex swallowing action of the animal. Any restraint, which interferes with this action is likely to reduce the chances of effecting a proper administration.

Note 2. 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.

Further Information
In areas where there is no known copper deficiency, no additional supplement of copper should be given to cattle, which have been administered Rumbul Bullets, for the active life of the bullets (4 weeks).

4.10 Overdose (Symptoms, emergency procedures, antidotes) if necessary

In the unlikely event of an accidental overdose, no special treatment is required

4.11 Withdrawal Periods for the various foodstuffs, including those for which the withdrawal period is zero

Meat – Zero days
Milk – Zero hours

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Rumbul Rumen Bullets for Cattle are a sustained release intraruminal device, supplying magnesium to supplement that available in the diet. The magnesium is released from the Bullets by electrolytic action, when in contact with reticulo rumen liquor, and is supplied continuously at a mean rate in the order of 1.43g/Bullet/day, throughout an active life of the Bullet of approximately 4 weeks. No permanent residue remains in the reticulo-rumen.

5.2 Pharmacokinetic particulars

Following oral administration, ionic magnesium is released into the reticulo rumen. The mechanism of action of the product is identical to dietary magnesium. Once absorbed, magnesium is stored in the body intracellularly in soft tissues and in bone. Magnesium absorbed in excess of body requirements is excreted in the urine.

Magnesium is an essential cofactor of many enzymes and for the normal physiology of neuromuscular function.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium
Copper
Iron Shot

6.2 Incompatibilities

None known.

6.3 Shelf life of the veterinary medicinal product as packaged for sale

10 years.

6.4 Special precautions for storage

Store in the original package
Keep the package tightly sealed
Store in a dry place

6.5 Nature and composition of immediate packaging

Rumbul Rumen Bullets – Cattle are moulded metal boluses packed in 10's in a 400 gauge polyethylene sleeve sealed at both ends. A 10-bullet sleeve is packed in a cardboard box (130 x 85 x 55mm), together with the pack leaflet.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products, if appropriate

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Agrimin Limited
Arlanda Way
Humberside Airport
Kirmington
North Lincolnshire
DN39 6YH

8. MARKETING AUTHORISATION NUMBER

Vm 04261/4003

9. DATE OF THE FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION

Date: 27th July 1993/27th July 2003.

10. DATE OF REVISION OF TEXT

Date: October 2011