Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Rumbul Rumen Bullet 15 g continuous release intraruminal device Sheep/Calves.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each bullet has a mass of 37g, comprising 17.44g (Mg-Al-Cu) alloy and 19.61g iron shot (ratio 47:53).

Active Substance:

Magnesium (in Mg-Al-Cu alloy)	15 g/bolus

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Continuous release intra-ruminal device.

4 CLINICAL PARTICULARS

4.1 Target Species

Sheep, calves.

4.2 Indications for use, specifying the target species

As an aid in the prevention of hypomagnesaemia in sheep of at least 30 kg bodyweight during the high risk period associated with early spring grazing after lambing.

As an aid in the prevention of hypomagnesaemia in suckling calves, of at least 50 kg bodyweight, where the diet is predominantly milk.

4.3 Contraindications

Do not use in sheep weighing less than 30 kg.
Do not use in calves weighing less than 50 kg.

4.4 Special warnings for each target species

Consumption of more than small amounts of other feeds (e.g. hay, silage, concentrates) may, by altering the pattern of rumen fermentation, change the rate of release of magnesium from the bullets.

Rumbul 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 small proportion of animals, which do not respond to the treatment. Rumbul 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 Bullets, for the active life of the bullets (3 weeks).

4.5 Special precautions for use

Special precautions for use in animals

See 4.9 below for precautions during administration.

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

None.

4.6 Adverse reactions (frequency and seriousness)

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 or 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.

4.7 Use during pregnancy, lactation or lay

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

Sheep

One Rumbul Sheep Bullet should be given to each animal 2 days before the expected period of risk, e.g. after lambing or transfer to new grazing. If necessary, dosing should be repeated after 3 weeks.

Calves

Two Rumbul Sheep Bullets should be given to each animal. One treatment should prevent a serious reduction in blood magnesium concentration for at least 3 weeks, thereafter, a repeat dose should be given if the calf is still receiving a predominantly milk diet.

Administer 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.

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 both bullets have been swallowed and not regurgitated.

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.

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 Period(s)

Edible Tissues and milk: zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Rumbul Rumen Bullets for Sheep are a sustained-release product, 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 0.5 g / Bullet / day, throughout an active life of the Bullet of approximately 3 weeks. No permanent residues remain in the reticulo-rumen.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium
Copper
Iron shot

6.2 Incompatibilities

Not applicable.

6.3 Shelf-life

Shelf life of the veterianry medicinal product as packaged for sale: 10 years.

6.4 Special precautions for storage

Partly used packs should be resealed, eg. with adhesive tape.
Store in a dry place, keep in original, sealed packs.

6.5 Nature and composition of immediate packaging

Moulded metal boluses packed in 10’s in a 400 gauge polyethylene sleeve sealed at both ends. Two 10-bullet sleeves are packed in a cardboard box (105 x 85 x 55mm), together with the pack leaflet.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10940/001/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2006

10 DATE OF REVISION OF THE TEXT

April 2012