IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007

(S.I. No. 786 of 2007)

VPA: **10960/049/001**
Case No: 7004527

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

Cross Vetpharm Group Ltd.

Broomhill Road, **Dublin 24**, **Ireland**

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Boviseal Dry cow intramammary infusion

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

The authorisation, unless previously revoked, shall continue in force from **29/06/2008**.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: From this date of effect, this authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Boviseal Dry cow intramammary infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance

Bismuth subnitrate	2.6g per 4g syringe

For a full list of excipients, see Section 6.1

3 PHARMACEUTICAL FORM

Intramammary infusion, dry cow.

Grey to white coloured cream.

4 CLINICAL PARTICULARS

4.1 Target Species

Dairy cows at the end of lactation.

4.2 Indications for use, specifying the target species

Boviseal is indicated for the prevention of new intramammary infections throughout the dry period. This results in a reduction in the incidence of subclinical mastitis in cows at calving, and of clinical mastitis in the dry period and the subsequent lactation (for at least 60 days after calving).

It is recommended that Boviseal be used as part of a herd approach to dry cow management and mastitis control. Cows considered likely to be free of subclinical mastitis should be given Boviseal at drying off according to the criteria below. Other animals should be managed in accordance with an approved mastitis control plan or specific veterinary advice.

For practical purposes, selection criteria may be based on the mastitis and cell count history of individual cows, or recognised tests for the detection of subclinical mastitis or bacteriological sampling. It is particularly important that, prior to treatment, an individual cell count be obtained from any cow with a history of clinical mastitis during the previous lactation. As a guide, cows with an average cell count less than 200,000 cells/ml before drying off may be given Boviseal. A minor increase (cell count up to 250,000 cells/ml) during the last 4 weeks before drying off is normal and may be ignored. In case of doubt, veterinary advice should be sought.

4.3 Contraindications

Do not use in the lactating cow.

4.4 Special warnings for each target species

Details provided above apply. See also point 4.2, 4.3 and 4.5.

4.5 Special precautions for use

Special precautions for use in animals

Not intended for use in cows with suspected or confirmed mastitis at drying off. If a sealed quarter develops clinical mastitis the affected quarter should be stripped out manually before appropriate antibacterial therapy is instituted.
For single use only.

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

None.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Boviseal should not be administered during lactation. If accidentally used in a lactating cow the seal should be stripped out manually and no additional precautions are needed.

Boviseal is safe for use in pregnant animals. At calving, the seal may be stripped out of the teat by hand or may be ingested by the calf. Ingestion of Boviseal by the calf is safe and produces no adverse effects.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For intramammary infusion.
Infuse the contents of one syringe of Boviseal into each udder quarter immediately after the last milking of the lactation (at drying off). Do not massage the teat or udder after infusion of the product

As Boviseal possesses no antimicrobial activity, it is essential that the teat is thoroughly cleaned, and that it is allowed to dry prior to infusion. Infuse aseptically and take care to avoid contamination of the syringe nozzle. Following infusion it is advisable to use an appropriate teat dip or spray.

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

Twice the recommended dose has been administered to cows with no adverse effects.

4.11 Withdrawal Period(s)

Meat and offal: zero days
Milk: zero days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Antibacterials for intramammary use.

ATCvet code: QJ51X

5.1 Pharmacodynamic properties

Infusion of Boviseal into each udder quarter produces a seal in the teat that provides an immediate and long lasting physical barrier to entry of bacteria and other mastitis causing organisms. By preventing new intramammary infections during the dry period Boviseal thereby also reduces the incidence of clinical mastitis in the next lactation.

5.2 Pharmacokinetic properties

Bismuth subnitrate is not absorbed from the mammary gland, but resides as a seal in the teat until physically removed. (Shown in cows with a dry period up to 100 days).

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid Paraffin
Aluminium Di Tri-Stearate
Colloidal Anhydrous Silica

6.2 Incompatibilities

None known.

6.3 Shelf-life

24 months

6.4 Special precautions for storage

Do not store above 25°C.

Keep out of the reach and sight of children.

6.5 Nature and composition of immediate packaging

A single dose intramammary syringe containing 4 g of a white to off-white intramammary paste.
Primary packaging: Low-density polyethylene syringe with a smooth, tapered hermetically sealed nozzle.
Marketing presentations: Boxes of 24, 60 and 120 syringes.

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

Cross Vetpharm Group Limited,
Broomhill Road,
Tallaght,
Dublin 24.

trading as Bimeda

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10960/049/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

29th June 2008

10 DATE OF REVISION OF THE TEXT