

IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10959/008/001**
Case No: 7005188

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:

Bimeda Holdings PLC
Broomhill Road, Tallaght, 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:

Multimast Dry Cow Intramammary Suspension

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 revoked, shall continue in force from **08/05/2009**.

Signed on behalf of the Irish Medicines Board

A person authorised in that behalf by the said Board.

(NOTE: 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

Multimast Dry Cow Intramammary Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 4.5 g syringe contains:

Active substance(s)

Neomycin sulphate	100 mg
Penethamate hydriodide	100 mg
Procaine benzylpenicillin	400 mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Intramammary suspension.

A smooth, off white, oily suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cows.

4.2 Indications for use, specifying the target species

For routine use in cows at drying off, to treat existing intramammary infections and to assist in preventing new infections occurring during the dry period.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.

Do not use in lactating cow.

Do not use within 50 days prior to calving

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precaution(s) for use in animals

None.

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

Operators should avoid contact with this preparation as occasionally skin allergy may occur.

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross reactions to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.

1. Do not handle this product if you know that you are sensitised, or if you have been advised not to work with such preparations.
2. Handle this product with care to avoid exposure, taking all the recommended precautions.
3. If you develop symptoms such as skin rash following exposure, seek medical advice and show this warning to the doctor. Swelling of the face, lips or eye, or difficulty with breathing are more serious symptoms and require urgent medical attention.

4.6 Adverse reactions (frequency and seriousness)

Other than the possibility of sensitivity reactions, it is not anticipated that the product will cause any undesirable effects due to the low toxicity of the actives and the method of administration of the product.

4.7 Use during pregnancy, lactation or lay

The product is not recommended for use within 50 days prior to calving. The product is not recommended for use in lactating cows, except at the drying off stage.

4.8 Interaction with other medicinal products and other forms of interaction

There is very little systemic absorption from the udder and the potential for interaction is thus extremely low.

4.9 Amounts to be administered and administration route

The contents of one syringe should be infused into each quarter via the teat canal immediately after the final milking of the lactation.

Before infusion, the teat should be thoroughly cleaned and disinfected and care should be taken to avoid contamination of the injector nozzle. Following infusion it is advisable to use a teat dip or spray.

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

Care should be taken not to overdose.

Overdosing may invalidate the stated milk and meat withdrawal times.

4.11 Withdrawal Period(s)

Milk for human consumption may only be taken after 96 hours post calving in cows with a dry period of more than 50 days.

Milk for human consumption may only be taken after 50 days plus 96 hours after the last treatment for cows with a dry period of 50 days or less.

Animals may not be slaughtered for human consumption until 28 days from the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Combination of antibacterials for intramammary use, Beta-lactam antibacterials with other antibacterials

ATCvet Code: QJ51RC

5.1 Pharmacodynamic properties

Multimast Dry Cow is an intramammary product intended for the administration to cows at drying off, to treat existing intramammary infections and to assist in preventing new infections occurring during the dry period.

The product contains an aminoglycoside (neomycin sulphate) and two penicillin derivatives (procaine benzyl penicillin and penethamate hydriodide).

Aminoglycosides disturb the permeability of the bacterial cell membrane by an effect exerted during cell wall development. Once the aminoglycoside has entered the cell, it binds to receptors on the ribosome, inducing misreading of the genetic code. Neomycin in common with other aminoglycosides has an activity predominately against gram negative organisms.

Penicillins act by interfering with microbial cell wall synthesis. They inhibit the activity of transpeptidase enzymes which catalyse cross linkage of the glycopeptide polymer units that form the cell wall.

Procaine benzyl penicillin is a complex, sparingly soluble organic salt of benzyl penicillin and its use is intended to delay release of the active penicillin moiety at the site of administration and so give rise to a longer duration of action than would be expected from benzyl penicillin.

Penethamate hydriodide is an ester of benzyl penicillin which is hydrolysed at pH 7.3 with the liberation of free penicillin. It therefore has the mode of action and spectrum of activity of benzyl penicillin.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid paraffin
Aluminium stearate

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years

Syringes are for single use only.

6.4 Special precautions for storage

Do not store above 25° C.

6.5 Nature and composition of immediate packaging

Polyethylene intramammary syringe, containing 4.5 g of an off-white oily intramammary suspension.

Syringes packed in buckets of 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 current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Bimeda Holdings Plc,
Broomhill Road,
Tallaght,
Dublin 24,
Ireland.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10959/008/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2007

10 DATE OF REVISION OF THE TEXT

8th June 2009