

IRISH MEDICINES BOARD ACT 1995

ANIMAL REMEDIES REGULATIONS, 2005

(S.I. No. 734 of 2005)

VPA: **10007/045/001**
Case No: 7002928

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies Regulations (S.I. No. 734 of 2005) hereby grants to:

Boehringer Ingelheim Ltd

Ellesfield Avenue, Bracknell, Berkshire RG12 8YS, England

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:

Four C 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.

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

Four C Dry Cow Intramammary Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml intramammary suspension contains:

Penethamate hydriodide	100 mg
Benethamine Penicillin	280 mg
Framycetin Sulphate	100 mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Intramammary suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle

4.2 Indications for use, specifying the target species

For routine treatment of subclinical infection present at drying off and to assist in the prevention of new infections during the dry period.

In vitro efficacy has been demonstrated against:

Staphylococcus spp.
Streptococcus spp.
Actinomyces (Corynebacterium) spp.
Escherichia coli
Klebsiella spp.
Pseudomonas spp

4.3 Contraindications

Do not use in the lactating cow.
Do not use in cases of known hypersensitivity to the active ingredients.
Not intended for use less than 28 days before calving.

4.4 Special warnings for each target species

Where there is a risk of summer mastitis, additional management procedures, such as fly control, should be considered.

4.5 Special precautions for use

Special precautions for use in animals

None.

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

Skin sensitisation may occur in persons handling this product, care should be taken to avoid contact with skin.

Penicillin and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillin may lead to cross sensitivity to cephalosporins and vice versa. Allergic reaction to these substances are occasionally serious.

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

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Product is safe for use in the pregnant cow

Use in the lactating cow is contraindicated.

4.8 Interaction with other medicinal products and other forms of interaction

None known

4.9 Amounts to be administered and administration route

The contents of one syringe to be infused into each quarter immediately after the last milking of a lactation. Before infusion, the teats 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

Not applicable

4.11 Withdrawal Period(s)

Milk for human consumption may only be taken 84 hours after calving.

If calving occurs before 28 days after last treatment, milk for human consumption may only be taken from 28 days plus 84 hours from the last treatment.

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

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Four C Dry Cow contains a combination of 3 antibiotics suspended in a slow release base specifically designed for dry cow therapy.

Following infusion the components are slowly released by the base and retained in the udder over a prolonged period. The penicillin components of Four C Dry Cow will remain in the dry udder for up to 3 weeks. In the majority of cows the framycetin component will remain in the dry udder for 10 to 14 weeks, or until “bagging up” prior to calving.

Benethamine penicillin and penethamate hydriodide have a similar range of activity and micro-organisms sensitive *in vitro* to the combination include streptococci, penicillin-sensitive staphylococci, corynebacteria and anaerobic micrococci. Micro-organisms sensitive *in vitro* to framycetin, include penicillin-resistant staphylococci, E. coli and other gram negative bacteria.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium Monostearate
Hydrogenated Castor Oil
Liquid Paraffin

6.2 Incompatibilities

None known.

6.3 Shelf-life

3 years.

6.4 Special precautions for storage

Do not store above 25⁰C.

6.5 Nature and composition of immediate packaging

Single-dose, pre-filled plastic syringe (cylinder with piston and cap, all made of polyethylene) containing 5 ml of a white, sterile, hydrophobic intramammary suspension. Injectors come in packs of 20 and 120.

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

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

Boehringer Ingelheim Ltd.
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10007/45/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2002

10 DATE OF REVISION OF THE TEXT

27th February 2007