1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Tetra-Delta Milking Cow

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 ml of suspension contains:
Active Substance
Neomycin (as Neomycin Sulphate) 105 mg
Novobiocin (as Novobiocin Sodium) 100 mg
Dihydrostreptomycin (as Dihydrostreptomycin Sulphate) 100 mg
Procaine Benzylpenicillin 100 mg
Prednisolone 10 mg
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Intramammary suspension.
Off white oily suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Lactating cattle.

4.2 Indications for use, specifying the target species

For the treatment of bovine mastitis in lactating cows.

4.3 Contraindications

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

4.4 Special warnings for each target species

If redness, irritation or swelling of the quarter persists, discontinue use and redetermine the diagnosis.
During a course of treatment the situation should be reviewed frequently by close veterinary supervision.

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

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

Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.

Handle this product with great care to avoid exposure taking all recommended precautions.

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 or eyes or difficulty in breathing are more serious symptoms and require urgent medical attention.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

This product may be used safely during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None.

4.9 Amounts to be administered and administration route

For intramammary administration.

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

Shake thoroughly before use.

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.

If necessary, in severe cases, treatment may be repeated once at a 24 or 48 hour interval.

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

Test milk for antibiotic residues before releasing for human consumption.

4.11 Withdrawal period(s)

Meat and offal: 7 days
Milk: 108 hours

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Combination of antibacterials for intramammary use, Antibacterials and corticosteroids
ATCvet Code: QJ51RV01

5.1 Pharmacodynamic properties

Tetra-Delta Milking Cow contains the antibiotics, procaine benzylpenicillin, novobiocin, dihydrostreptomycin and neomycin. It also contains the anti-inflammatory corticosteroid, prednisolone. The penicillin provides maximum activity against streptococci with potentiation contributed by dihydrostreptomycin. The novobiocin provides maximum activity against both beta-lactamase and non-beta-lactamase producing *Staphylococcus aureus* and also inhibits penicillin-resistant L-form production in the presence of penicillin.

The dihydrostreptomycin component provides cover against *Escherichia coli* in instances where there is neomycin resistance and also potentiates the anti-streptococcal activity of penicillin. The neomycin provides principal activity

against *E.coli* and provides cover in instances where there is dihydrostreptomycin resistance. The prednisolone exerts anti-inflammatory activity which reduces swelling and associated pain.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium Monostearate
Arachis Oil.

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 18 months.
The syringe may only be used once. Part used syringes must be discarded.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

12ml low density polyethylene syringe filled to 10ml with a sterile suspension.
Low density polyethylene plunger.
Low density polyethylene base cap.
Low density polyethylene tip cap.
Cardboard box containing 24 x 10ml syringes.

The Flexi-tube offers two tip lengths: one for full insertion, or one for partial insertion.

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

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

Zoetis Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park, Loughlinstown
Co Dublin
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10387/078/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1987
Date of last renewal: 29th October 2008

10 DATE OF REVISION OF THE TEXT

July 2017