SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TETRA-DELTA™ Intramammary Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 ml of suspension contains:

Novobiocin Sodium equal to Novobiocin	100 mg
Neomycin Sulphate equal to Neomycin	105 mg
Procaine Penicillin	100 mg
Dihydrostreptomycin Sulphate equal to Dihydrostreptomycin	100 mg
Prednisolone	10 mg

For the full list of all other 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 cattle.

4.3 Contraindications

None.

4.4 Special warnings for each target species

If redness, irritation or swelling of the quarter persists, discontinue use and re-determine the diagnosis.

4.5 Special precautions for use

i. Special precautions for use in animals

During a course of treatment the situation should be reviewed frequently by close veterinary supervision.

ii. 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.

Wash hands after use.

Eye Contact: Immediately flush the eye with copious amounts of clean running water.

Skin Contact: Wash the affected area thoroughly.

Ingestion: If accidentally swallowed, seek medical attention and show product label and/or pack insert to the doctor.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

No restriction.

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 administration.

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

Shake container 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)

Cattle (meat and offal): 7 days
(milk): 108 hours

5. PHARMACOLOGICAL PROPERTIES

Tetra-Delta Milking Cow contains the antibiotics, procaine penicillin G, 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 *Escherichia 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.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

10-ml white, low density polyethylene syringes.
Natural, low density polyethylene plunger.
Red, high density polyethylene base cap.
White, low density polyethylene tip cap.

Available in cardboard cartons containing 24 syringes.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

8. MARKETING AUTHORISATION NUMBER

Vm 42058/4152

9. DATE OF THE FIRST AUTHORISATION

29 March 1985

10. DATE OF REVISION OF THE TEXT

November 2020

Approved 06 November 2020