PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {Syringe label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tetra-Delta™ Intramammary Suspension

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 10 ml contains:

Novobiocin (as novobiocin sodium)	100 mg
Neomycin (as neomycin sulphate)	105 mg
Procaine Penicillin	100 mg
Dihydrostreptomycin (as dihydrostreptomycin sulphate)	100 mg
Prednisolone	10 mg

3. PHARMACEUTICAL FORM

Intramammary Suspension

Sterile Suspension

4. PACKAGE SIZE

10 ml

5. TARGET SPECIES

6. INDICATION(S)

For the treatment of bovine mastitis, in lactating cattle only, by intramammary infusion.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Directions: Shake container before use. Infuse the contents of one syringe into each infected quarter. If necessary, in severe cases, the treatment may be repeated once at 24 or 48 hour intervals.

See package leaflet for warnings, contra-indications, operator warnings etc.

8. WITHDRAWAL PERIOD

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

9. SPECIAL WARNING(S), IF NECESSARY

Penicillins and cephalosporins may occasionally cause severe allergic reactions. During treatment the situation should be reviewed frequently by close veterinary supervision.

10. EXPIRY DATE

EXP.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V

To be supplied only on veterinary prescription

For animal treatment only

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4152

17. MANUFACTURER'S BATCH NUMBER

LOT

MFG

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tetra-Delta™ Intramammary Suspension

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 10 ml contains:

Novobiocin (as novobiocin sodium)	100 mg
Neomycin (as neomycin sulphate)	105 mg
Procaine Penicillin	100 mg
Dihydrostreptomycin (as dihydrostreptomycin sulphate)	100 mg
Prednisolone	10 mg

3. PHARMACEUTICAL FORM

Intramammary Suspension

Sterile Suspension

4. PACKAGE SIZE

24 x 10 ml syringes with Flexi-Tube™

5. TARGET SPECIES

Lactating cattle

6. INDICATION(S)

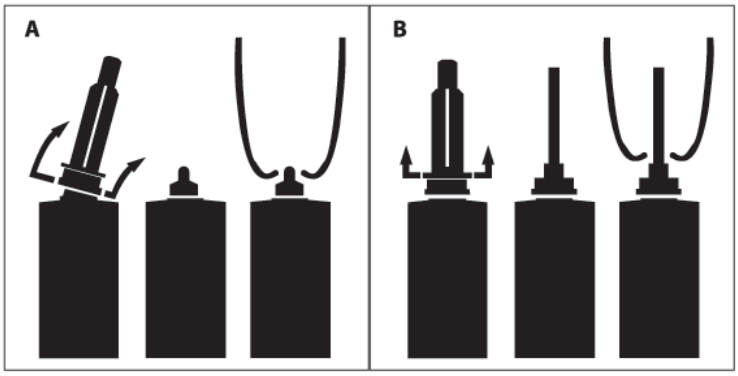
For the treatment of bovine mastitis, in lactating cattle only, by intramammary infusion.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Directions: Shake container before use. After milking, clean and disinfect the teat of each infected quarter. Infuse the contents of one syringe into each infected quarter. If necessary, in severe cases, the treatment may be repeated once at 24 or 48 hour intervals.

Flexi-Tube™
The Flexi-Tube™ offers two tip lengths: one for full insertion and one for partial insertion (recommended to help preserve the teat canals' natural defence against disease).

A. PARTIAL INSERTION
Remove both the white end cap and red cannula by grasping between the thumb and forefinger and snapping sideways as shown. Gently insert the exposed white tip into the teat canal; carefully infuse the product.



B. FULL INSERTION
Remove the white end cap by pulling straight up as shown. Gently insert the full cannula into the teat canal; carefully infuse the product.

8. WITHDRAWAL PERIOD

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

9. SPECIAL WARNING(S), IF NECESSARY

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

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

The syringe may only be used once.

Operator warnings:
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 package leaflet to the doctor.

10. EXPIRY DATE

EXP.:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Part used syringes must be discarded.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulatory authority.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V

To be supplied only on veterinary prescription

For animal treatment only

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4152

17. MANUFACTURER'S BATCH NUMBER

LOT:

MFG:

PACKAGE LEAFLET FOR: Tetra-Delta™ Intramammary Suspension

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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

Batch release site not stated

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tetra-Delta™ Intramammary Suspension

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

A sterile white suspension. Each 10 ml contains: Novobiocin (as novobiocin sodium) 100 mg, Neomycin (as neomycin sulphate) 105 mg, Procaine penicillin 100 mg, Dihydrostreptomycin (as dihydrostreptomycin sulphate) 100 mg and Prednisolone 10 mg in an oily base.

4. INDICATION(S)

For the treatment of bovine mastitis in lactating cows.

5. CONTRAINDICATIONS

-

6. ADVERSE REACTIONS

-

7. TARGET SPECIES

Lactating cattle.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Intramammary use. Shake well before use.

After milking, clean and disinfect the teat of each infected quarter. Infuse the contents of one syringe into each infected quarter.

9. ADVICE ON CORRECT ADMINISTRATION

TETRA-DELTA should be shaken thoroughly before use.

Following infusion, it is advisable to use a teat dip or spray.

10. WITHDRAWAL PERIOD(S)

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

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

12. SPECIAL WARNING(S)

Operator warnings:
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.

If necessary, in severe cases, treatment may be repeated once at a 24 or 48 hour intervals. During a course of treatment the situation should be reviewed frequently by close veterinary supervision.

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

For animal treatment only.

Keep out of the sight and reach of children.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

February 2021

15. OTHER INFORMATION

POM-V

To be supplied only on veterinary prescription.

Vm 42058/4152

Supplied in boxes of 24 x 10 ml disposable syringe with Flexi-Tube™.

Approved: 18/03/21