ANNEX II

A. MANUFACTURERS RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

A. MANUFACTURERS RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturers responsible for batch release

Norbrook Laboratories Limited
Station Works, Camlough Road,
Newry, County Down,
BT35 6JP
UNITED KINGDOM

or

Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

The printed package leaflet of the medicinal product must state the name and address of the manufacturer responsible for the release of the concerned batch.

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

The active substance in Pirsue 5 mg/ml intramammary solution for cattle is an allowed substance as described in table 1 of the annex to Commission Regulation (EU) No 37/2010:

Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Pirlimycin	Pirlimycin	Bovine	100 µg/kg 100 µg/kg 1000 µg/kg 400 µg/kg 100 µg/kg	Muscle Fat Liver Kidney Milk	NO ENTRY	Anti-infectious agents/ Antibiotics

The excipients listed in section 6.1 of the SPC are considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

8 syringes x10 ml in an outer carton box
24 syringes x10 ml in an outer carton box, including 3 package inserts
120 syringes x10 ml in a plastic bucket, including 15 package inserts

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pirsue 5 mg/ml intramammary solution for cattle

2. STATEMENT OF ACTIVE SUBSTANCES

Pirlimycin (as Pirlimycin hydrochloride) 50 mg/10 ml.

3. PHARMACEUTICAL FORM

Intramammary solution

4. PACKAGE SIZE

8 intramammary syringes x10 ml
24 intramammary syringes x10 ml
120 intramammary syringes x10 ml

5. TARGET SPECIES

Cattle (lactating dairy cows).

6. INDICATION(S)

For the treatment of subclinical mastitis in lactating cows due to Gram-positive cocci susceptible to pirlimycin including staphylococcal organisms such as *Staphylococcus aureus*, both penicillinase-positive and penicillinase-negative, and coagulase-negative staphylococci; streptococcal organisms including *Streptococcus agalactiae*, *Streptococcus dysgalactiae* and *Streptococcus uberis.*

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramammary use.

Read the package leaflet before use.

Infuse one syringe (50 mg pirlimycin) into each infected quarter.
Treatment consists of eight infusions of one syringe every 24 hours.

Care must be taken not to introduce pathogens into the teat in order to reduce the risk of *E. coli* infections. Ensure adequate cleansing of the teat (and udder - if needed) before infusion.

Insertion: Remove the white end cap by pulling straight up. Gently insert the cannula into the teat canal; carefully infuse the product.
Push plunger with continuous pressure gently and slowly to dispense entire contents into the gland and massage the quarter to distribute the product into the milk cistern.
Following infusion, dip all teats with a disinfectant teat dip.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Meat and offal: 23 days.
Milk: 5 days.

9. SPECIAL WARNING(S), IF NECESSARY

Avoid contact with the solution. Wash hands and any exposed skin with soap and water and remove contaminated clothing immediately after use. Flush eyes with water for 15 minutes immediately after exposure. Hold eyelids open to ensure complete contact with water.
Cross-resistance may occur between pirlimycin and other lincosamides or macrolides.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C. Keep the syringes in the outer carton.

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

Disposal: read package leaflet.

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

For animal treatment only. To be supplied only on veterinary prescription.

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 42058/5045

17. MANUFACTURER'S BATCH NUMBER

Lot{number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{label on the syringe}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pirsue 5 mg/ml

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

50 mg Pirlimycin

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 ml

4. ROUTE(S) OF ADMINISTRATION

Intramammary use.

5. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Meat and offal: 23 days.
Milk: 5 days.

6. BATCH NUMBER

Lot{number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Pirsue 5 mg/ml intramammary solution for cattle

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

Marketing authorisation holder:

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

Manufacturer responsible for batch release:

Norbrook Laboratories Limited
Station Works, Camlough Road,
Newry, County Down,
BT35 6JP
UNITED KINGDOM

or

Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pirsue 5 mg/ml intramammary solution for cattle

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

Pirlimycin (as Pirlimycin hydrochloride) 50 mg/10 ml

4. INDICATION(S)

For the treatment of subclinical mastitis in lactating cows due to Gram-positive cocci susceptible to pirlimycin including staphylococcal organisms such as *Staphylococcus aureus*, both penicillinase-positive and penicillinase-negative, and coagulase-negative staphylococci; streptococcal organisms including *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, and *Streptococcus uberis.*

5. CONTRAINDICATIONS

Resistance against pirlimycin.
Treatment of infections due to Gram-negative bacteria such as *E. coli*.
Do not treat cows with palpable udder changes due to chronic subclinical mastitis.

6. ADVERSE REACTIONS

None known.

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle (lactating dairy cows).

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

Intramammary use.

Infuse one syringe (50 mg pirlimycin) into each infected quarter.
The treatment consists of eight infusions of one syringe every 24 hours.

9. ADVICE ON CORRECT ADMINISTRATION

Care must be taken not to introduce pathogens into the teat in order to reduce the risk of *E. coli* infections. Ensure adequate cleansing of the teat (and udder - if needed) before infusion. The following instructions should therefore be followed carefully.
Clean hands before handling the cow's udder. Wash the udder if it is dirty. Where necessary, wash the teats thoroughly with warm water containing a suitable dairy cleansing agent and dry them thoroughly. Disinfect teat end using a suitable cleansing agent. The teat end should be cleaned until no more dirt appears on the swab. Use a separate disinfectant towelette for each teat. Do not touch cleaned teat ends before administering the infusion substance.

Insertion: Remove the white end cap by pulling straight up. Gently insert the cannula into the teat canal; carefully infuse the product.
Push plunger with continuous pressure gently and slowly to dispense entire contents into the gland and massage the quarter to distribute the product into the milk cistern.
Following infusion, dip all teats with a disinfectant teat dip.

Susceptibility testing of the target bacteria should be carried out prior to treatment.

10. WITHDRAWAL PERIOD(S)

Meat and offal: 23 days.
Milk: 5 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 25 °C. Keep the syringes in the original container.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and the container.

12. SPECIAL WARNING(S)

Avoid contact with the solution. Wash hands and any exposed skin with soap and water and remove contaminated clothing immediately after use. Flush eyes with water for 15 minutes immediately after exposure. Hold eyelids open to ensure complete contact with water.
Cross-resistance may occur between pirlimycin and other lincosamides or macrolides.

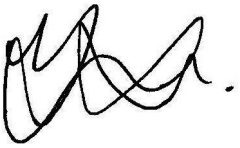
13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Not all pack sizes may be marketed.



Approved: 30 June 2021