SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pirsue 5 mg/ml intramammary solution for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Pirlimycin (as Pirlimycin hydrochloride) 50 mg/10 ml

For the full list of excipients see Section 6.1

3. PHARMACEUTICAL FORM

Intramammary solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle (lactating dairy cows).

4.2 Indications for use, specifying the target species

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.*

4.3 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.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

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

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

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.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

The product is indicated for use in lactating dairy cows and can be used during pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction

Cross-resistance may occur between pirlimycin and other lincosamides or macrolides.

4.9 Amounts to be administered and administration route

Administration: by intramammary infusion only.

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. 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 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.

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

No data on overdosing are available.

4.11 Withdrawal period(s)

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

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterial for intramammary use.
ATCvet code: QJ51FF90.

5.1 Pharmacodynamic properties

Pirlimycin hydrochloride is a semi-synthetic lincosamide antibiotic. The lincosamides (clindamycin, lincomycin, and pirlimycin) inhibit protein synthesis in Gram-positive and in anaerobic bacteria as well as in *Mycoplasma* spp. They work by binding to the 50S ribosomal subunit, therefore hindering the aminoacyl-tRNA binding and inhibiting the peptidyltransferase reaction, which interferes with protein synthesis within the bacteria. Gram-positive isolates with an MIC > 2 µg/ml are to be considered resistant. Enteric bacteria such as *E. coli* are intrinsically resistant to pirlimycin.

Pirlimycin has a basic pKa (8.5). This means it will be more active in an acid environment and tends to concentrate, relative to plasma, in areas with lower pH, such as abscesses. Pirlimycin has been shown to accumulate in polymorphonuclear cells, however, intracellular killing of *Staphylococcus aureus* was not demonstrated.

5.2 Pharmacokinetic particulars

After intramammary infusion, mean parent concentrations in milk were 10.3 µg/ml at 12 hours and 0.77 µg/ml at 24 hours. Similar concentrations were reached at 12 and 24 hours after a second infusion at a 24 hour interval. Of the dose infused, 10-13% is excreted in the urine, and 24-30% via the faeces; the remainder is excreted in the milk.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Anhydrous citric acid
Sodium citrate
Water for injection

6.2 Major incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

6.4 Special precautions for storage

Do not store above 25 °C. Keep the syringes in the original container.

6.5 Nature and composition of immediate packaging

Polyethylene intramammary syringes (containing 10 ml sterile aqueous solution), packaged in cardboard boxes containing 8 or 24 syringes. Also packaged as 120 syringes in a plastic bucket.

Not all pack sizes may be marketed.

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

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 42058/5045

9. DATE OF FIRST AUTHORISATION

29 January 2001

10. DATE OF REVISION OF THE TEXT

June 2021

Approved: 30 June 2021