# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Mastiplan LC, 300mg/20mg (Cefapirin/Prednisolone), intramammary suspension for lactating cows

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each syringe of 8g suspension contains:

**Active substance(s):**
300 mg cefapirin as cefapirin sodium
20 mg Prednisolone

**Excipients:**
For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Intramammary suspension
Off-white/yellow to pink, oily, homogenous suspension

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Cattle (Lactating dairy cows)

### 4.2 Indications for use, specifying the target species

Treatment of clinical mastitis in lactating dairy cows caused by *Staphylococcus aureus,* Coagulase negative *staphylococci*, *Streptococcus agalactiae, Streptococcus dysgalactiae, Streptococcus uberis* and *Escherichia coli* sensitive to cefapirin.

### 4.3 Contraindications

Do not use in cases of hypersensitivity to cephalosporins, other □-lactam antibiotics or to any of the excipients.

### 4.4 Special warnings for each target species

None.

### 4.5 Special precautions for use

Special precautions for use in animals

Do not use the cleaning towels on teats with open wounds.

Official, national and regional antimicrobial policies should be taken into account when the product is used. Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria. Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the cefapirin and may decrease the effectiveness of the treatment.

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 cephalosporin and vice versa. Allergic reactions to these substances may occasionally be serious.
Do not handle this product if you know you are sensitised to penicillins or cephalosporins or if you have been advised not to work with such preparation.
Handle this product with 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. Swellings of the face, lips or eyes or difficulty breathing are more serious symptoms and require urgent medical attention.
Wash hands after using the cleaning towels and wear protective gloves if skin irritation due to isopropyl alcohol is known or suspected.

## 4.6 Adverse reactions (frequency and seriousness)

In very rare cases immediate hypersensitivity reactions may occur.

The frequency of adverse reactions is defined using the following convention:

-very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
-common (more than 1 but less than 10 animals in 100 animals)
-uncommon (more than 1 but less than 10 animals in 1,000 animals)
-rare (more than 1 but less than 10 animals in 10,000 animals)
-very rare (less than 1 animal in 10,000 animals, including isolated reports).

## 4.7 Use during pregnancy, lactation or lay

The veterinary medicinal product is intended for use during lactation.
Laboratory studies in mice, rats, rabbits, and hamster have not produced any evidence of a teratogenic, foetotoxic, maternotoxic effects.
Because no specific studies have been performed in the target animal species, use only according to the benefit/risk assessment by the responsible veterinarian during pregnancy and in breeding animals.

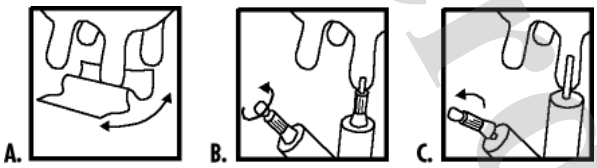
## 4.8 Interaction with other medicinal products and other forms of interaction

The concurrent use with bacteriostatic antibiotics may cause antagonistic effects.

The concurrent use of parenteral aminoglycosides or other nephrotoxic drugs is not recommended.

### 4.9 Amounts to be administered and administration route

The contents of one syringe should be infused into each affected quarter via the teat canal, immediately after milking, at 12 hour intervals for four consecutive milkings. Each syringe contains 300 mg cefapirin and 20 mg prednisolone. The syringe must only be used once for one teat.
Before infusion, the udder should be milked out completely. The teat and its orifice should be thoroughly cleaned and disinfected with the cleaning towel provided (A). Care should be taken to avoid contamination of the syringe nozzle. Break the top of cap and gently insert either about 5 mm (B) or remove whole cap and gently insert the total length of the nozzle (C) into the teat canal. Infuse the total content of the syringe into the quarter.
Disperse the product by gentle massage of the teat and the udder of the affected cow.




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

None known.

### 4.11 Withdrawal period(s)

Meat and offal: 4 days (96 hours)
Milk: 5.5 days (132 hours)

## 5. PHARMACOLOGICAL PROPERTIES

ATC vet code: QJ51RV01
Pharmacotherapeutic group: Antibacterials for intramammary use, combinations of antibacterials and corticosteroids.

### 5.1 Pharmacodynamic properties

Cefapirin is a first generation cephalosporin which acts by inhibition of cell wall synthesis. It is bactericidal with a time dependant mechanism of action and is characterised by its broad therapeutic spectrum of activity.
*In vitro* activity has been demonstrated against common Gram positive and Gram negative bacteria including *Escherichia coli, Staphylococcus aureus,* coagulase negative *Staphylococci, Streptococcus dysgalactiae, Streptococcus agalactiae*, and *Streptococcus uberis*.
An overview of the $MIC_{50}$ and $MIC_{90}$ values of common bacterial mastitis pathogens collected for a resistance monitoring programme (VetPath programme from the European Animal Health Study Centre (CEESA)) is presented in the table below

(except for data regarding *Streptococcus agalactiae*, which were gathered during clinical trials conducted between 1984 and 2005):

| **Bacterial species isolated** | **N** | **$MIC_{50}$ (µg/ml)** | **$MIC_{90}$ (µg/ml)** |
|---|---|---|---|
| *Staphylococcus aureus* | 192 | 0.12 | 0.25 |
| coagulase negative Staphylococci | 165 | 0.12 | 0.25 |
| *Streptococcus uberis* | 188 | 0.25 | 0.5 |
| *Streptococcus dysgalactiae* | 95 | 0.06 | 0.06 |
| *Streptococcus agalactiae* | 58 | 0.25 | 0.25 |
| *Escherichia coli* | 207 | 16 | >32 |

During the last 10 years only an increase in the $MIC_{90}$ values of *E.coli* was observed.

Prednisolone exerts anti-inflammatory properties through the inhibition of the early and the late phases of inflammation. After intramammary application, prednisolone induces a reduction in the swelling and subsequent size of the infected quarter and promotes a return to normal temperature in infected animals.

### 5.2 Pharmacokinetic particulars

After intramammary administration of Mastiplan LC, cefapirin and prednisolone are mainly excreted via milk during milking. The absorption of both cefapirin and prednisolone into the blood stream is fast and limited. The absorbed fractions of both cefapirin and prednisolone are mainly excreted in urine.

An overview of the concentrations of cefapirin and prednisolone in milk during treatment is presented in the table below:

| Active substance | Mean milk concentrations of active substances at milking relative to first treatment | | | | |
|---|---|---|---|---|---|
| | 0 | 1st milking | 2nd milking | 3rd milking | 4th milking |
| Cefapirin (µg/mL) | 0 | 27.0 ± 6.2 | 30.2 ± 7.9 | 40.0 ± 8.8 | 34.6 ± 6.5 |
| Prednisolone (ng/mL) | 0 | 182.0 ± 61.7 | 100.8 ± 51.0 | 283.7 ± 129.8 | 101.5 ± 38.8 |

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

- Glycerol Monostearate
- Calcium Sodium Aluminosilicate
- Arachis oil, refined.

### 6.2 Incompatibilities

Not applicable.

## 6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years

## 6.4 Special precautions for storage

Store below 25°C.
Keep the syringes in the aluminium sachets and the outer carton.

## 6.5 Nature and composition of immediate packaging

**Nature of the packaging**:
A 10 mL polyethylene syringe composed of three parts:

- cylinder
- plunger
- cap

The syringes are thereafter inserted in laminated aluminium foiled sachets.

**Pack sizes:**
Box of 1 sachet of 4 syringes and 4 cleaning towels.
Box of 1 sachet of 20 syringes and 20 cleaning towels.

Not all pack sizes may be marketed.

**Cleaning towels:**
Paper cleaning towels moistened in isopropyl alcohol 70% v/v solution (2.4 ml/towel).

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

## 7. MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

## 8. MARKETING AUTHORISATION NUMBER

Vm 01708/4534

## 9. DATE OF FIRST AUTHORISATION

25 May 2007

## 10. DATE OF REVISION OF THE TEXT

August 2020

Approved 14 August 2020