MSD Animal Health UK Limited

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

Species: Cattle

Therapeutic indication:Pharmaceuticals: Antimicrobials: Intramammaries: Lactating cow

Active ingredient: Cephapirin, Prednisolone

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

Product index: Mastiplan® LC

Cattle - milk:132 hours

Cattle - meat:4 days

Incorporating:

Qualitative and quantitative composition

Each 8 g syringe contains:

Active substances:

300 mg cefapirin as cefapirin sodium

20 mg Prednisolone

Excipients: For the full list of excipients, see section "Pharmaceutical Particulars".

Pharmaceutical form

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

Clinical particulars

Target species

Cattle (lactating cows).

Indications for use

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.

Contraindications

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

Special warnings for each target species

None.

Special precautions for use

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

Use of the product should be based on identification and susceptibility testing of the target pathogens. If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.

Use of the product should be in accordance with official, national and regional antimicrobial policies.

An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

The feeding of waste milk containing residues of cefapirin to calves should be avoided up to the end of the milk withdrawal period (except during the colostral phase), because it could select antimicrobial-resistant bacteria within the intestinal microbiota of the calf and increase the faecal shedding of these 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.

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 cephalosporin and vice versa. Allergic reactions to these substances may occasionally be serious.

People with known hypersensitivity to cephalosporins, penicillins or prednisolone should avoid contact with the veterinary medicinal product.

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 immediately and show the package leaflet or the label to the physician. 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.

Adverse reactions

Cattle (Lactating cows):

Very rare (<1 animal / 10,000 animals treated, including isolated reports):

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See also “Contact details” of the package leaflet.

Use during pregnancy or lactation

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.

Interactions

The concurrent use with bacteriostatic antibiotics may cause antagonistic effects.

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

Amounts to be administered and administration route

For intramammary use:

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.

Overdose

None known.

Withdrawal periods

Meat and offal: 4 days (96 hours)

Milk: 5.5 days (132 hours).

Pharmacological particulars

ATCvet code: QJ51RV01

Pharmacotherapeutic group

Antibacterials for intramammary use, combinations of antibacterials and corticosteroids.

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 MIC50 and MIC90 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**	**MIC50 (µg/ml)**
Staphylococcus aureus	192	0.12
Coagulase negative staphylococci	165	0.12
Streptococcus uberis	188	0.25
Streptococcus dysgalactiae	95	0.06
Streptococcus agalactiae	58	0.25
Escherichia coli	207	16

During the last 10 years only an increase in the MIC90 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

Pharmacokinetic properties

After intramammary administration of the veterinary medicinal product, 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		
	0 **1st milking**	**2nd milking**	**3rd milking**
Cefapirin (µg/ml)	0 27.0 ± 6.2	30.2 ± 7.9	40.0 ± 8.8
Prednisolone (ng/ml)	0 182.0 ± 61.7	100.8 ± 51.0	283.7 ± 129.8

Pharmaceutical particulars

Excipients

Glycerol monostearate

Sodium calcium aluminosilicate

Arachis oil, refined

Major incompatibilities

Not applicable.

Shelf life

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

Special precautions for storage

Store below 25 °C.

Keep the syringes in the aluminium sachets and the outer carton.

Immediate 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).

Disposal

Medicines should not be disposed of via wastewater.

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

Marketing Authorisation Holder (if different from distributor)

Intervet International B.V., represented by MSD Animal Health UK Limited.

Marketing Authorisation Number

UK (GB): Vm 06376/5004

UK (NI): Vm 06376/3004

Significant changes

Date of the first authorisation or date of renewal

25 May 2007.

Date of revision of the text

December 2024.

Any other information

For animal treatment only. Keep out of the sight and reach of children.

Legal category

Legal category:POM-V

GTIN

NOAH Compendium

GTIN description: Mastiplan LC 1x20 inj:

GTIN:8713184067470