PARTICULARS TO APPEAR ON THE OUTER PACKAGE
CARTON BOX (4 and 20 syringes)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Each 8 g syringe of suspension contains:
300 mg cefapirin as cefapirin sodium
20 mg prednisolone

3. PACKAGE SIZE

4 syringes and 4 cleaning towels
20 syringes and 20 cleaning towels

4. TARGET SPECIES

Cattle (lactating cows)

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramammary use.

7. WITHDRAWAL PERIODS

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

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

14. MARKETING AUTHORISATION NUMBERS

Vm 06376/3004

15. BATCH NUMBER

Lot {number}

Proposed text to appear on printed packaging for UK(NI) under Article 13 of Veterinary Medicine Regulations 2019/6 if joint labelled with UK(GB)

User warnings
Penicillins and cephalosporins may occasionally cause severe allergic reactions.
See package leaflet for user warnings.

Dispose of waste material in accordance with local requirements.

POM-V To be supplied only on veterinary prescription.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

SYRINGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Mastiplan LC

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each 8 g syringe contains:
300 mg cefapirin as cefapirin sodium
20 mg prednisolone

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Proposed text to appear on printed packaging for UK(NI) under Article 13 of Veterinary Medicine Regulations 2019/6 if joint labelled with UK(GB)

8 g

Intramammary use.

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

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

SACHET

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Mastiplan LC

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each 8 g syringe of suspension contains:
300 mg cefapirin as cefapirin sodium
20 mg prednisolone

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

3. Target species

Cattle (lactating cows)

4. 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.

5. Contraindications

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

6. Special warnings

Special precautions for safe use in the target species:
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 pathogen. 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.

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 leadto 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 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.

Pregnancy and lactation:
The veterinary medicinal product is intended for use during lactation.
Laboratory studies in mice, rats, rabbits, and hamster have not produced any evidenceof 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.

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 notrecommended.

7. Adverse events

Cattle (lactating cows)

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

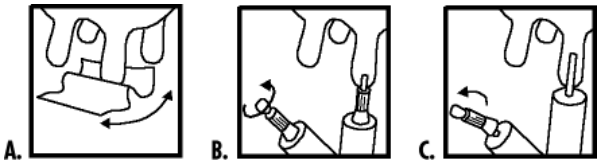
Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

8. Dosage for each species, routes and method of administration

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. Thesyringe must only be used once for one teat.

9. Advice on correct administration

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 thetotal length of the nozzle (C) into the teat canal. Infuse the total content of the syringeinto the quarter.
Disperse the product by gentle massage of the teat and the udder of the affected cow.



10. Withdrawal periods

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

11. Special storage precautions

Keep out of the sight and reach of children.

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

Store below 25 °C.

Do not use this veterinary medicinal product after the expiry date which is stated onthe label and carton after EXP. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.
Dispose of waste material in accordance with local requirements.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Marketing authorisation number:
Vm 06376/3004

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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

Manufacturers responsible for batch release:
Intervet International GmbH
Feldstrasse 1A
85716 Unterschleissheim
Germany

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

Contact details to report suspected adverse reactions:
Intervet Ireland Ltd.
Tel.: +353 (0)1 2970220

Distributor in Northern Ireland:
Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24, Ireland

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

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 andthe late phases of inflammation. After intramammary application, prednisolone inducesa reduction in the swelling and subsequent size of the infected quarter and promotes a return to normal temperature in infected animals.
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 duringtreatment 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

Gavin Hall
Approved: 09 December 2024