SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lactatrim MC Intramammary Suspension.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 8g syringe contains:

Active Substances:	**mg**
Trimethoprim	40
Sulfadiazine.	200

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Intramammary suspension.
White to off-white suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle (lactating)

4.2 Indications for use, specifying the target species

An intramammary suspension for the broad spectrum treatment of clinical mastitis in the lactating cow.

Effective against gram-positive and gram-negative bacteria including *Streptococcus agalactiae, Streptococcus dysgalactiae, Streptococcus uberis* and other streptococcal species, *Staphylococcal* spp, *Actinomyces pyogenes, Eschericha coli*, and other gram-negative bacteria.

4.3 Contraindications

Do not use in cattle with known sulphonamide sensitivity.

4.4 Special Warnings for each target species

Do not use in cattle with hepatic damage or blood dyscrasias.

4.5 Special precautions for use

Official, national and regional antimicrobial policies should be taken into account when the product is used.

i. Special precautions for use in animals

None.

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

Take care to avoid skin and eye contact. Gloves should be worn whilst handling this product. Wash hands and exposed skin after use.
Sulphonamides may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to sulphonamides may lead to cross reactions with other antibiotics. Allergic reactions to these substances may occassionally be serious.

1. Do not handle this product if you know you are sensitive to sulphonamides.
2. If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

Lactatrim MC is safe for use during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

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 three consecutive milkings. Clean and disinfect the teat before each treatment.

The syringe may only be used once.

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

Not applicable.

4.11 Withdrawal period

Cattle:
Meat - 7 days

Milk - 48 hours

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterial

ATC Vet Code: QJ01EE02

5.1 Pharmacodynamic properties

The product contains trimethoprim and sulfadiazine as the active ingredients which act with a unique "double-blockade" mode of action. Each component disrupts a different vital link in the metabolic chain used by susceptible bacteria to make nucleic acids and proteins.

Sulfadiazine inhibits the incorporation of p-amino benzoic (PABA) acid into dihydrofolic acid.

Sulfadiazine specifically competes with PABA for the enzyme dihydropteroate synthetase, this selective bacteriostatic action depending on the difference between bacterial and mammalian cells in the source of folic acid. Susceptible microorganisms synthesise folic acid, whereas mammalian cells use preformed folic acid.

Trimethoprim selectively inhibits the enzyme dihydrofolate reductase thereby preventing the conversion of dihydrofolic acid into tetrahydrofolic acid, this sequential enzymatic blockage resulting in a synergistic effect and enhanced activity at the site of infection when the two compounds are present.

Thus trimethoprim greatly potentiates the antimicrobial activity of sulphonamides both *in vitro* and *in vivo*.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydrogenated Caster oil,
Arachis Oil.

6.2 Incompatibilities

None known.

6.3 Shelf life

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

6.4 Special precautions for storage

Do not store above 25ºC.

6.5 Nature and composition of immediate packaging

8g syringe (12ml capacity) with high density polyethylene barrel and low density polyethylene plunger closed with end cap, 6 individual syringes presented in a blister pack of aluminium foil and clear polyvinyl chloride.
A carton containing 24 syringes.

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 material derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Listow Limited
9 Belgrave Square
London
SW1X 8PH

8. MARKETING AUTHORISATION NUMBER(S)

Vm 41687/4000

9. DATE OF FIRST AUTHORISATION

Date: 4 March 1997

10. DATE OF REVISION OF THE TEXT

Date: October 2012