Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Framomycin 150 mg/ml Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance
Framycetin Sulphate 150 mg (90,000 IU)
Excipients
Chlorocresol 1 mg
Sodium metabisulphite (E223) 2 mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.
Clear, pale yellow solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Dairy cows.

4.2 Indications for use, specifying the target species

For use as an adjunct to intramammary therapy in the treatment of acute bacterial mastitis with systemic involvement, caused by organisms sensitive to framycetin in dairy cows. In vitro, framycetin has shown activity against *Escherichia coli*, *Staphylococcus aureus*, *Arcanobacterium pyogenes* and *Klebsiella* spp.

4.3 Contraindications

Do not administer by the intravenous route, for intramuscular use only. Do not administer to animals known to be allergic to framycetin or other Streptomyces produced aminoglycosides, (e.g. streptomycin, gentamicin, kanamycin or neomycin). Hypersensitivity to framycetin may lead to cross reactions to other Streptomyces-produced aminoglycosides and vice versa.

4.4 Special warnings for each target species

None known.

4.5 Special precautions for use

i) Special precautions for use in animals

The aminoglycosides can cause a fall in serum calcium levels: the concomitant use of calcium borogluconate infusions at the time of parturition may be advisable.
Patients' water intake should not be restricted during treatment.

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

Avoid the introduction of contamination during use. Should any apparent growth or discolouration occur, the product should be discarded.
Care should be taken to avoid accidental self injection.
If irritation occurs, seek medical attention, showing the product label to a doctor.
Allergy (hypersensitivity) to framycetin containing products can lead to cross reactions with those products containing other Streptomyces-produced aminoglycosides. Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Framycetin can be nephrotoxic and ototoxic and the recommended dose and dosage range should not be exceeded.
The drug is excreted in the urine and should, therefore, be used with caution in patients with compromised renal function. Patient's water intake should not be restricted during treatment.

4.7 Use during pregnancy, lactation or lay

Use according to the benefit/risk assessment of the responsible veterinary surgeon.

4.8 Interaction with other medicinal products and other forms of interactions

Cephalosporins may potentiate the toxicity of the aminoglycosides and should not be used concurrently.

4.9 Amounts to be administered and administration route

1 ml per 30 kg bodyweight (equivalent to 5 mg active ingredient per kg bodyweight) by intramuscular injection. Doses should be administered twice daily and treatment should be continued for a maximum of 3 days.

Parenteral Framomycin injections should be given in conjunction with an appropriate intramammary preparation.

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

May lead to potentially irreversible ototoxic or nephrotoxic effects. Do not exceed the stated dose.

4.11 Withdrawal period(s)

Meat and offal: 135 days
Milk: 60 hours

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use,
Aminoglycoside antibacterials, Other aminoglycosides.
ATCvet code: QJ01GB91

5.1 Pharmacodynamic properties

Framycetin belongs to the aminoglycoside group of antimicrobials which have a rapid dose-related bactericidal action on susceptible microorganisms. Once inside the cell, it binds to receptors on the 30S subunit of the ribosome which induces misreading of the genetic code during transcription, so inhibiting ribosomal protein synthesis.

5.2 Pharmacokinetic particulars

Aminoglycosides are poorly absorbed from the gastrointestinal tract and bind to a low extent to plasma proteins. Elimination is by renal excretion as the unchanged drug. Framomycin 150 mg/ml Solution for Injection is readily absorbed from the intramuscular injection site and does not give rise to local reactions.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chlorocresol
Sodium metabisulphite (E223)
Sodium citrate dihydrate (E331)
Citric acid anhydrous (E330)
Water for injection

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product should not be mixed with other veterinary medicinal products.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf-life after first opening the immediate packaging: 21 days.

6.4 Special precautions for storage

Do not store above 25°C.
Protect from light.
Following withdrawal of the first dose, use the product within 21 days.

6.5 Nature and composition of immediate packaging

Carton containing single 100 ml vial
Container: Amber, Type I glass vial
Closure: Chlorobutyl rubber bung with aluminium overseal

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

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

7 MARKETING AUTHORISATION HOLDER

Elanco GmbH
Heinz-Lohmann-Strasse 4
27472 Cuxhaven
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA22020/025/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1998
Date of last renewal: 30th September 2008

10 DATE OF REVISION OF THE TEXT

July 2018