

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Framomycin 150 mg/ml Solution for Injection

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

**1 ml contains:**

**Active substance:**

Framycetin sulphate 150 mg (90,000 IU)

**Excipients:**

Chlorocresol 1 mg  
Sodium metabisulphite (E223) 2 mg

For the 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 interaction**

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 periods for the various foodstuffs including those for which the withdrawal period is zero**

Meat and offal: 135 days  
Milk: 60 hours

### **5 PHARMACOLOGICAL 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 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 of 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 product 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 Europe Ltd  
Lilly House  
Priestley Road  
Basingstoke  
Hampshire  
RG24 9NL

## **8. MARKETING AUTHORISATION NUMBER**

Vm 00879/4033

## **9. DATE OF FIRST AUTHORISATION**

25 October 1994

## **10. DATE OF REVISION OF THE TEXT**

March 2016

 16 March 2016