# ANNEX III

# LABELLING AND PACKAGE LEAFLET

# A. LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**NATURE/TYPE: Cardboard box (label)**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Framomycin 150 mg/ml Solution for Injection

## 2. STATEMENT OF ACTIVE SUBSTANCES

Sterile, aqueous solution containing framycetin sulphate 150 mg/ml (90,000 IU per ml), chlorocresol 1 mg/ml and sodium metabisulphite 2 mg/ml as preservatives.

## 3. PHARMACEUTICAL FORM

Solution for Injection

## 4. PACKAGE SIZE

12 x 100 ml

## 5. TARGET SPECIES

Dairy cows
<Picture of cow>

## 6. INDICATION(S)

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 *E. coli, Staphylococcus aureus*, *Arcanobacterium (Actinomyces) pyogenes* and *Klebsiella* spp.

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

See package leaflet for full details.
1 ml per 30 kg bodyweight (equivalent to 5 mg active ingredient per kg of bodyweight) by intramuscular injection. Doses should be administered twice daily and treatment should be continued for a maximum of 3 days. Parenteral framycetin injections should be given in conjunction with an appropriate intramammary preparation.

## 8. WITHDRAWAL PERIOD(S)

Withdrawal periods: Meat and offal - 135 days. Milk - 60 hours.

## 9. SPECIAL WARNING(S), IF NECESSARY

See package leaflet for full advice.
Care should be taken to avoid accidental self injection. Wash hands after use.

## 10. EXPIRY DATE

EXP:
Following withdrawal of the first dose, use remainder of the product within 21 days.

## 11. SPECIAL STORAGE CONDITIONS

See package leaflet for full details.
Do not store above 25ºC.
Protect from light.
Keep container in outer carton.
Discard unused material.

## 12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

See package leaflet for advice on disposal.

## 13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.
As an item for sale or supply only from a pharmacy by a pharmacist on the prescription of a registered veterinary surgeon or by a registered veterinary surgeon for the treatment of animals under his/her care.

POM-V

POM Prescription Only Medicine

## 14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of sight and reach of children.

## 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd.,
Lilly House, Priestley Road,
Basingstoke, Hampshire,
RG24 9NL, UK.
Tel: 01256 353131

## 16. MARKETING AUTHORISATION NUMBER(S)

UK: Vm 00879/4033
IE: VPA 10397/009/001

## 17. MANUFACTURER'S BATCH NUMBER

Bn:

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

**NATURE/TYPE: Glass Vial**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Framomycin 150 mg/ml Solution for Injection

## 2. STATEMENT OF ACTIVE SUBSTANCES

Sterile, aqueous solution containing framycetin sulphate 150 mg/ml (90,000 IU per ml), chlorocresol 1 mg/ml and sodium metabisulphite 2 mg/ml as preservatives.

## 3. PHARMACEUTICAL FORM

Solution for Injection

## 4. PACKAGE SIZE

100 ml

## 5. TARGET SPECIES

Dairy cows
<Picture of cow>

## 6. INDICATION(S)

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 *E. coli, Staphylococcus aureus, Arcanobacterium (Actinomyces) pyogenes* and *Klebsiella* spp.

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

See package leaflet for full details.
1 ml per 30 kg bodyweight (equivalent to 5 mg active ingredient per kg of bodyweight) by intramuscular injection. Doses should be administered twice daily and treatment should be continued for a maximum of 3 days. Parenteral framycetin injections should be given in conjunction with an appropriate intramammary preparation.

## 8. WITHDRAWAL PERIOD(S)

Withdrawal periods: Meat and offal - 135 days. Milk - 60 hours.

## 9. SPECIAL WARNING(S), IF NECESSARY

See package leaflet for full advice.
Care should be taken to avoid accidental self injection. Wash hands after use.

## 10. EXPIRY DATE

EXP:
Following withdrawal of the first dose, use remainder of the product within 21 days.
Date of broaching _____
Date of discard _____

## 11. SPECIAL STORAGE CONDITIONS

See package leaflet for full details.
Do not store above 25ºC.
Protect from light.
Keep container in outer carton.
Discard unused material.

## 12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

See package leaflet for advice on disposal.

## 13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.
As an item for sale or supply only from a pharmacy by a pharmacist on the prescription of a registered veterinary surgeon or by a registered veterinary surgeon for the treatment of animals under his/her care.

POM-V

POM Prescription Only Medicine

## 14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of sight and reach of children.

## 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd.,
Lilly House, Priestley Road,
Basingstoke, Hampshire,
RG24 9NL, UK.
Tel: 01256 353131

## 16. MARKETING AUTHORISATION NUMBER(S)

UK: Vm 00879/4033
IE: VPA 10397/009/001

## 17. MANUFACTURER'S BATCH NUMBER

Bn:

# B. PACKAGE LEAFLET

# PACKAGE LEAFLET:
# Framomycin 150 mg/ml Solution for Injection

## 1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Elanco Europe Ltd.,
Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL, UK.
Tel: 01256 353131

Manufacturer responsible for batch release:
Bela-Pharm GmbH & Co. KG Lohner Straße 19
49377 Vechta
Germany

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Framomycin 150 mg/ml Solution for Injection

## 3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Framomycin 150 mg/ml Solution for Injection is a sterile, aqueous solution containing framycetin sulphate 150 mg/ml (90,000 IU per ml) and chlorocresol 1 mg/ml and sodium metabisulphite 2 mg/ml as preservatives.

## 4. INDICATION(S)

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 *E. coli, Staphylococcus aureus, Arcanobacterium (Actinomyces) pyogenes* and *Klebsiella* spp.

## 5. 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).

## 6. ADVERSE REACTIONS

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. Patients' water intake should not be restricted during treatment.

## 7. TARGET SPECIES

Dairy cows

## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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

## 9. ADVICE ON CORRECT ADMINISTRATION

For animal treatment only.
Parenteral framycetin injections should be given in conjunction with an appropriate intramammary preparation.
The aminoglycosides can cause a fall in calcium levels: the concomitant use of calcium borogluconate infusion at the time of parturition may be advisable.

## 10. WITHDRAWAL PERIOD(S)

Meat and offal - 135 days.
Milk - 60 hours.

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 25°C.
Protect from light.
Keep container in outer carton.
Following withdrawal of the first dose, use remainder of the product within 21 days.
When the container is broached (opened) for the first time, calculate the discard date. This should be 21 days from the date of first broaching (opening) and should be written in the space provided for this purpose on the vial label. Discard unused material.

## 12. SPECIAL WARNING(S)

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Allergy (hypersensitivity) to framycetin-containing products can lead to cross reactions with those products containing other Streptomyces-produced aminoglycosides.
Care should be taken to avoid accidental self injection If irritation occurs, seek medical attention, showing the product label to a doctor.
Wash hands after use.

Interaction with other medicinal products and other forms of interaction:
Cephalosporins may potentiate the toxicity of the aminoglycosides and should not be used concurrently.

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

## 13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

## 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

## 15. OTHER INFORMATION

**Package Quantities:** 100 ml amber glass multidose vial.
Framomycin 150 mg/ml Solution for Injection is readily absorbed from the intramuscular injection site and does not give rise to local reactions.

**Legal Category:**
To be supplied only on veterinary prescription. Prescription Only Medicine
POM-V POM
As an item for sale or supply only from a pharmacy by a pharmacist on the prescription of a registered veterinary surgeon or by a registered veterinary surgeon for the treatment of animals under his/her care.

**Marketing Authorisation Number:** Vm 00879/4033, VPA 10397/009/001

**Approved: 26/04/2017**