ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box for 100 mL and 250 mL vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RESFLOR 300/16.5 mg/mL Solution for Injection

2. STATEMENT OF ACTIVE SUBSTANCES

300 mg/ml florfenicol
16.5 mg/ml flunixin (as flunixin meglumine)

3. PACKAGE SIZE

100 mL
250 mL

4. TARGET SPECIES

Cattle

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For subcutaneous use.

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 46 days
Milk: Not authorised for use in animals producing milk for human consumption. Do not use in pregnant animals which are intended to produce milk for human consumption within 2 months of expected parturition.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use within 28 days.
Once opened, use by ….

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Do not freeze.
Protect from frost.
Keep the vial in 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

MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
MK7 7AJ

14. MARKETING AUTHORISATION NUMBERS

Vm 01708/3014

15. BATCH NUMBER

Lot {number}

User warning:
Care should be taken to avoid accidental self-injection and serious caution should be taken in women of childbearing age, pregnant women or women suspected of being pregnant.

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

Excipients:
250 mg/ml N-methyl-2-pyrrolidone
150 mg/ml propylene glycol E1520

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

POM-V To be supplied only on veterinary prescription.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label for the 100 mL and 250 mL vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RESFLOR 300/16.5 mg/mL Solution for Injection

2. STATEMENT OF ACTIVE SUBSTANCES

300 mg/ml florfenicol
16.5 mg/ml flunixin (as flunixin meglumine)

3. TARGET SPECIES

Cattle

4. ROUTES OF ADMINISTRATION

For subcutaneous use. Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 46 days
Milk: Not authorised for use in animals producing milk for human consumption. Do not use in pregnant animals which are intended to produce milk for human consumption within 2 months of expected parturition.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use within 28 days.
Once opened, use by….

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Do not freeze.
Protect from frost.
Keep the vial in the outer carton.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
MK7 7AJ

9. BATCH NUMBER

Lot {number}

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

Excipients:
250 mg/ml N-methyl-2-pyrrolidone
150 mg/ml propylene glycol E1520

100 mL
250 mL

Care should be taken to avoid accidental self-injection.
Swab septum before removing each dose. Use a dry sterile needle and syringe.

For animal treatment only.

POM-V To be supplied only on veterinary prescription.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

RESFLOR 300/16.5 mg/mL Solution for Injection for Cattle

2. Composition

Each mL contains:

Active substances:

Florfenicol	300.0 mg
Flunixin	16.5 mg equivalent to 27.4 mg flunixin meglumine

Excipients:

Propylene Glycol (Antimicrobial Preservative) E1520	150.0 mg
N-Methyl-2-Pyrrolidone	250.0 mg

Clear, light yellow to straw coloured liquid.

3. Target species

Cattle.

4. Indications for use

Treatment of respiratory infections caused by *Mannheimia haemolytica*, *Pasteurella multocida, Mycoplasma bovis* and *Histophilus somni* associated with pyrexia.

5. Contraindications

Do not use in adult bulls intended for breeding purposes.
Do not use in animals suffering from hepatic and renal diseases.
Do not use if there is a risk of gastrointestinal bleeding or in cases where there is evidence of altered hemostasis.
Do not use in animals suffering from cardiac diseases.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

6. Special warnings

Special precautions for safe use in the target species:
Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.
Official and local antimicrobial policies should be taken into account when the product is used.

Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to florfenicol.
Avoid use in dehydrated, hypovolaemic or hypotensive animals as there is a potential risk of increased renal toxicity. Concurrent administration of potentially nephrotoxic drugs should be avoided.
Repeated daily dosing has been associated with abomasal erosions in the pre-ruminant calf. The product should be used with caution in this age group. The safety of the product has not been tested in calves of 3 weeks of age or less.

Flunixin is toxic to avian scavengers. Do not administer to animals susceptible to enter wild fauna food chain. In case of death or sacrifice of treated animals, ensure that they are not made available to wild fauna.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Care should be taken to avoid accidental self-injection.
People with known hypersensitivity to propylene glycol and polyethylene glycols should avoid contact with the veterinary medicinal product.
Wash hands after use.
Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Women of childbearing age, pregnant women or women suspected of being pregnant should use the veterinary medicinal product with serious caution to avoid accidental self-injection.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established in cattle during pregnancy, lactation or in animals intended for breeding.
Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Use only according to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
Concurrent use of other active substances that have a high degree of protein binding may compete with flunixin for binding and thus lead to toxic effects.
Pre-treatment with other anti-inflammatory substances may result in additional or increased adverse effects and accordingly a treatment-free period with such drugs should be observed for at least 24 hours before the commencement of treatment. The treatment-free period, however, should take into account the pharmacokinetic properties of the products used previously.
The product must not be administered in conjunction with other NSAIDs or glucocorticosteroids. Gastrointestinal tract ulceration may be exacerbated by corticosteroids in animals given NSAIDs.

Overdose:
Overdose studies in the target species for 3 times the duration of treatment showed decreased food consumption in the groups given 3 and 5 times the recommended dose. Decreased body weights were observed in the 5 times

overdose group (secondary to decreased food consumption). Decreased water consumption was observed in the 5 times overdose group. Tissue irritation increases with injection volume.
Treatment at 3 times the recommended treatment duration was associated with dose-related erosive and ulcerative abomasum lesions.

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

Cattle:

Very common (>1 animal / 10 animals treated):
Injection site swelling[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Anaphylactic-type reaction (severe form of allergic reaction)[2]

[1]becomes palpable 2-3 days after subcutaneous injection. The duration of the injection site swellings ranged from 15-36 days post-injection. Grossly, this is associated with minimal to mild irritation of the subcutis. Extension into the underlying muscle was noted in only a few instances. By 56 days post-dosing, no gross lesions were observed that would require any trim-out at slaughter.
[2]these reactions may be fatal.

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:
Email: adverse.events@vmd.gov.uk
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

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

Subcutaneous use.
40 mg/kg florfenicol and 2.2 mg/kg flunixin (2 ml/15 kg body weight) to be administered by a single injection.

9. Advice on correct administration

Swab septum before removing each dose. Use a dry sterile needle and syringe.
To ensure a correct dosage, bodyweight should be determined as accurately as possible.

The dose volume given at any one injection site should not exceed 10 ml.
The injection should only be given in the neck.
It is recommended to treat animals in the early stages of the disease and to evaluate the response to treatment 48 hours after injection. The anti-inflammatory component of the veterinary medicinal product, flunixin, may mask a poor bacteriological response to florfenicol in the first 24 hours after injection. If clinical signs of respiratory disease persist or increase, or if relapse occurs, treatment should be changed, using another antibiotic, and continued until clinical signs have resolved.

10. Withdrawal periods

Meat and offal: 46 days
Milk: Not authorised for use in animals producing milk for human consumption. Do not use in pregnant animals which are intended to produce milk for human consumption within 2 months of expected parturition.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25°C.
Do not freeze.
Protect from frost.

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

Shelf life after first opening the immediate packaging: 28 days.

When the container is broached for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of 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

Vm 01708/3014

Carton box containing 100 ml vial
Carton box containing 250 ml vial

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

October 2023

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

16. Contact details

Marketing authorisation holder:
MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer responsible for batch release:
Vet Pharma Friesoythe
Sedelsberger Strasse 2
26169 Friesoythe
Germany

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

Environmental properties
Flunixin is toxic to avian scavengers although foreseen low exposure leads to low risk.

Approved 09 November 2023