A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Folding box for 100 ml and 250 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Flovuxin 300/16.5 mg/ml solution for injection for cattle

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains: 300 mg florfenicol and 16.5 mg flunixin (as flunixin meglumine).

3. PACKAGE SIZE

100 ml
250 ml

4. TARGET SPECIES

Cattle

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

Withdrawal period(s):
Meat and offal: 46 days.
Milk: Not authorised for use in animals producing milk for human consumption. Do not use during lactation or drying off periods. 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 broached use within 28 days.
Once broached use by……

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.
Store in the original package.

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

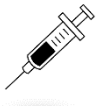
KRKA

14. MARKETING AUTHORISATION NUMBERS

Vm 01656/3033

15. BATCH NUMBER

Lot {number}



PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{Glass bottles of 100 ml and 250 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Flovuxin 300/16.5 mg/ml solution for injection for cattle

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains: 300 mg florfenicol and 16.5 mg flunixin (as flunixin meglumine).

100 ml
250 ml

3. TARGET SPECIES

Cattle

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.
Subcutaneous use.

5. WITHDRAWAL PERIODS

Withdrawal period(s):
Meat and offal: 46 days.
Milk: Not authorised for use in animals producing milk for human consumption. Do not use during lactation or drying off periods. 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 broached use within 28 days.
Once broached use by……

7. SPECIAL STORAGE PRECAUTIONS

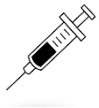
Do not store above 25 °C.
Store in the original package.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

KRKA

9. BATCH NUMBER

Lot {number}



B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Flovuxin 300/16.5 mg/ml solution for injection for cattle

2. Composition

Each ml contains:

Active substances:

Florfenicol	300.0 mg
Flunixin (as flunixin meglumine)	16.5 mg

Excipients:

Propylene glycol E1520	150.0 mg

Solution for injection is a clear, slightly yellow to yellow or to greenish yellow solution or to brownish yellow solution.

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:
This product may cause adverse effects. Care should be taken to avoid accidental self-injection.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

This veterinary medicinal product may cause hypersensitivity reactions (allergy). People with known hypersensitivity to propylene glycol and polyethylene glycols should avoid contact with the veterinary medicinal product. If you develop symptoms following exposure, such as skin rash, swelling of the face, lips or eyes or difficulty with breathing, you should seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands after use.

Pregnancy and lactation:
The effect of florfenicol on bovine reproductive performance, pregnancy and lactation has not been assessed. Use only accordingly 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.

Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance:
For administration only by a veterinarian.

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

7. Adverse events

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Anaphylactic-type reaction[1]
Undetermined frequency:
Application site swelling[2]

[1]Those reactions might be fatal.
[2]Subcutaneous administration of the product may result in application site swelling that become palpable 2-3 days after injection. The duration of the application site swelling 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.

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 using the contact details at the end of this leaflet, or via your national reporting system https://www.gov.uk/report-veterinary-medicine-problem.

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

Subcutaneous use.
40 mg of florfenicol per kg bodyweight and 2.2 mg of flunixin per kg bodyweight (equivalent to 2 mL of product per 15 kg body weight) to be administered by a single subcutaneous injection.

9. Advice on correct administration

Swab septum before removing each dose. Use a dry sterile needle and syringe.
To ensure correct dosage and avoid underdosing, bodyweight should be determined as accurately as possible.
The dose volume given at any one injection site should not exceed 10 ml.
The cap may be safely punctured up to 25 times. When treating groups of animals in one run, use a draw-off needle that has been placed in the vial stopper to avoid excess broaching of the stopper. The draw-off needle should be removed after treatment.
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 this veterinary product, flunixin, may mask resistance 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 during lactation or drying off periods. 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.
Store in the original package.

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

Shelf life after first opening the immediate packaging: 28 days

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 product should be disposed of in accordance with local requirements.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 01656/3033

Type II clear glass bottles of 100 ml and type I clear glass bottles of 250 ml with type I bromobutyl rubber stoppers and aluminium caps with plastic tear/flip-off tabs, in a cardboard box.

Package sizes:
Cardboard box containing 1 bottle of 100 ml.
Cardboard box containing 1 bottle of 250 ml.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

March 2023

Detailed information on this veterinary medicinal product is available in the Union Product Database.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

Manufacturer responsible for batch release:
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia
TAD Pharma GmbH, Heinz-Lohmann-Straße 5, 27472 Cuxhaven, Germany

17. Other information

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

Approved 17 March 2023