PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton with one (1) bottle of 50, 100, 250 or 500 mL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FLORGANE 300 mg/mL Suspension for Injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each mL contains:
Florfenicol 300 mg

3. PACKAGE SIZE

50 mL
100 mL
250 mL
500 mL

4. TARGET SPECIES

Cattle, pigs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Shake before use.
Intramuscular use.
One injection of 30 mg florfenicol per kg BW (1 mL/10 kg) in cattle and of 22.5 mg florfenicol per kg BW (0.75 mL/10 kg) in pigs.

7. WITHDRAWAL PERIODS

Withdrawal period:
Cattle (meat and offal): 37 days.
Not authorised for use in animals producing milk for human consumption.
Pigs (meat and offal): 22 days.

8. EXPIRY DATE

Exp. *{mm/yyyy}*

Shelf life after first opening: 28 days.
Once broached use by: …….

9. SPECIAL STORAGE PRECAUTIONS

Protect from light.
Do not refrigerate or freeze.

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

Emdoka bvba

14. MARKETING AUTHORISATION NUMBER

Vm 34534/3002

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

GROUP PACKAGING: Carton with 12x50 mL, 12x100 mL, 12x250 mL or 12x500 mL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FLORGANE 300 mg/mL Suspension for Injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each mL contains:
Florfenicol 300 mg

3. PACKAGE SIZE

12 x 50 mL
12 x 100 mL
12 x 250 mL
12 x 500 mL

4. TARGET SPECIES

Cattle, pigs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Shake before use.
Intramuscular use.
One injection of 30 mg florfenicol per kg BW (1 mL/10 kg) in cattle and of 22.5 mg florfenicol per kg BW (0.75 ml/10 kg) in pigs.

7. WITHDRAWAL PERIODS

Withdrawal period:
Cattle (meat and offal): 37 days.
Not authorised for use in animals producing milk for human consumption.
Pigs (meat and offal): 22 days.

8. EXPIRY DATE

Exp. *{mm/yyyy}*

Shelf life after first opening: 28 days.
Once broached use by: …….

9. SPECIAL STORAGE PRECAUTIONS

Protect from light.
Do not refrigerate or freeze.

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

Emdoka bvba

14. MARKETING AUTHORISATION NUMBER

Vm 34534/3002

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label for bottles of 50 mL, 100 mL, 250 mL and 500 mL.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FLORGANE 300 mg/mL Suspension for Injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each mL contains :
Florfenicol 300 mg

3. TARGET SPECIES

Cattle, pigs.

4. ROUTES OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:
Cattle (meat and offal): 37 days.
Not authorised for use in animmals producing milk for human consumption.
Pigs (meat and offal): 22 days.

6. EXPIRY DATE

Exp. *{mm/yyyy}*

Shelf life after first opening: 28 days.
Once broached use by:……

7. SPECIAL STORAGE PRECAUTIONS

Protect from light.
Do not refrigerate or freeze.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Emdoka

9. BATCH NUMBER

Lot {number}

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Florgane 300 mg/mL Suspension for Injection for Cattle and Pigs

2. Composition

Each mL contains:

Active substance:
Florfenicol 300 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
n-Butanol	10 mg
Potassium metabisulfite (E 224)	0.2 mg

White to yellowish-white suspension.

3. Target species

Cattle, pigs.

4. Indications for use

Cattle:
Preventive and therapeutic treatment of respiratory tract infections in cattle caused by florfenicol susceptible *Mannheimia haemolytica, Pasteurella multocida* and *Histophilus somni*. The presence of the disease in the herd should be established before treatment.

Pigs:
Treatment of acute outbreaks of respiratory disease caused by strains of *Actinobacillus pleuropneumoniae* and *Pasteurella multocida* susceptible to florfenicol.

5. Contraindications

Do not use in adult bulls and boars intended for breeding purposes.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special precautions for safe use in the target species:
Do not use in piglets of less than 2 kg.
Use of the veterinary medicinal 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 national and regional antimicrobial policies should be taken into account when the veterinary medicinal product is used.
Use of the veterinary medicinal product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to florfenicol and may decrease the effectiveness of treatment with other antimicrobials, due to the potential for cross-resistance.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to florfenicol or to one of the ingredients of the veterinary medicinal product should avoid contact with this veterinary medicinal product.
Avoid contact with skin and eyes. In case of dermal contact, wash the exposed area immediately with water.
Do not smoke, eat or drink while handling this veterinary medicinal product.
Take care to avoid accidental self-injection.
If such symptoms as skin rash appear after being exposed to this veterinary medicinal product, seek for medical advice. Face, lip or eye swelling, as well as difficult breathing, are serious signs requiring urgent medical assistance.

Pregnancyand lactation:
Studies in laboratory animals have not produced any evidence of embryo- or foetotoxic potential for florfenicol.
However, the effect of florfenicol on bovine reproductive performance and pregnancy has not been assessed. Use only according to the benefit-risk assessment by the responsible veterinarian.
The safety of the veterinary medicinal product in sows during pregnancy and lactation has not been established. Use of the veterinary medicinal product during pregnancy and lactation is therefore not recommended.

Overdose:
Cattle: None.
Pigs: Parenteral overdoses of florfenicol in swine may cause a reduction in feeding, hydration and weight gain, and vomiting.

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:

Undetermined frequency (cannot be estimated from the available data)	Injection site swelling[1], injection site inflammation[2] Soft stool[3,4] Allergic reaction Reduced food intake[3]

[1] After intramuscular injection, usually resolves within 5 days but may persist for more than 5 days up to beyond 21 days.

2 May persist for 18 days after administration.

3 During treatment period, the treated animals recover quickly and completely upon termination of treatment.

4 Transient.

Pigs:

Very common (1 animal / 10 animals treated)	Diarrhoea[1, 2] Oedematous erythema[1,3]
Undetermined frequency (cannot be estimated from the available data)	Injection site swelling[4], injection site inflammation[5] Allergic reaction

[1] Transient.

[2] Disappear without treatment within 6 days.

[3] Peri-anal and rectal, may persist up to 1-2 weeks after treatment.

[4] Mild, after intramuscular injection, usually resolves within 6 days but may persist up to beyond 12 days.

[5] Macroscopic inflammatory lesions resolve between 12 and 20 days after administration.

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.

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

Cattle:
Intramuscular use.
By one single administration in the neck musculature**:**
30 mg of florfenicol per kg body weight (eq. to 1 mL of the veterinary medicinal product per 10 kg body weight).
Do not inject more than 15 mL per injection site in cattle.

Pigs:
Intramuscular use.
By one single administration behind the ears: 22.5 mg of florfenicol per kg body weight (eq. to 0.75 mL of the veterinary medicinal product per 10 kg body weight).
Do not inject more than 5 mL per injection site in pigs.

In cattle over 150 kg and in pigs over 65 kg the total injection volume must be divided over two or more injections sites while always respecting the maximum injection volume of 15 mL per injection site in cattle and of 5 mL per injection site in pigs. Injections may be given in alternate sides of the neck.
In case injections are given in cattle at the same side of the neck, the minimum distance between injection sites always must be 15 to 20 cm.

To ensure a correct dosage, body weight should be determined as accurately as possible.

Shake before use.
Use a dry, sterile needle and syringe. Swab septum before removing each dose.
For 50 and 100 mL bottles, do not broach the vial more than 25 times. For 250 and 500 mL bottles, do not broach the vial more than 50 times.

Another type of treatment needs to be considered if response to treatment is inadequate.

9. Advise on correct administration

None.

10. Withdrawal periods

Cattle:
Meat and offal: 37 days.
Not authorised for use in animals producing milk for human consumption.
Pigs:
Meat and offal: 22 days.

11. Special storage precautions

Keep out of the sight and reach of children.

Protect from light. Do not refrigerate or freeze.
Do not use after the expiry date stated on the label 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 the wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems.These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 34534/3002

Pack sizes:
Bottles with 50, 100, 250 or 500 mL of suspension for injection.
Carton containing either:
1 or 12 x 50 mL,
1 or 12 x 100 mL,
1 or 12 x 250 mL,
1 or 12 x 500 mL.
Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. Contact details

Marketing authorisation holder:
Emdoka bvba, John Lijsenstraat 16, B-2321 Hoogstraten, Belgium.
Tel: +32 (0) 3 315 04 26, info@emdoka.be

Manufacturer responsible for batch release:
Produlab Pharma bv, Forellenweg 16, NL-4941 SJ Raamsdonksveer,
The Netherlands.

Local representatives and contact details to report suspected adverse reactions:

Gavin Hall
Approved: 18 December 2024