

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE
BOX**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

KEFLORIL 300 mg/ml Solution for injection for cattle and pigs
Florfenicol

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Florfenicol.....300 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml
100 ml
250 ml

5. TARGET SPECIES

Already mentioned in the name.

6. INDICATION(S)

Not included

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Pigs: Intramuscular route 1 ml/20kg (15 mg/kg bodyweight) into the neck muscle twice at 48-hour intervals. The volume administered per injection site should not exceed 3 ml.

Cattle:

For treatment:

IM route: 20 mg/kg bodyweight (1 ml/15 kg) to be administered twice 48 hours

SC route: 40 mg/kg bodyweight (2 ml/15 kg) to be administered once

The dose volume given at any one injection site should not exceed 10 ml.

For prevention:

SC route: 40 mg/kg bodyweight (2 ml/15 kg) to be administered once

The dose volume given at any one injection site should not exceed 10 ml.

The injection should only be given in the neck.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Pigs

Meat and offal: 18 days

Cattle

Meat and offal: by IM (at 20 mg/kg bodyweight, twice): 30 days

by SC (at 40 mg/kg bodyweight, once): 44 days

Milk: Not permitted for use in lactating animals producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

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

Once broached, use by

11. SPECIAL STORAGE CONDITIONS

Not applicable.

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

Disposal: read package leaflet.

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.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr Alderton
Towcester
Northamptonshire
NN12 7LS

16. MARKETING AUTHORISATION NUMBER

Vm 08007/4123

17. MANUFACTURER'S BATCH NUMBER
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Batch {number}

MINIMUM PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
Label of 100 and 250 ml vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

KEFLORIL 300 mg/ml Solution for injection for cattle and pigs
Florfenicol

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Florfenicol.....300 mg/ml

3. PHARMACEUTICAL FORM

Not requested

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

Already mentioned in the name.

6. INDICATION(S)

Not included

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Pigs: Intramuscular route 1 ml/20kg (15 mg/kg bodyweight) into the neck muscle twice at 48-hour intervals. The volume administered per injection site should not exceed 3 ml.

Cattle: Intramuscular or Subcutaneous route

For treatment:

IM route: 20 mg/kg bodyweight (1 ml/15 kg) to be administered twice 48 hours

SC route: 40 mg/kg bodyweight (2 ml/15 kg) to be administered once

The dose volume given at any one injection site should not exceed 10 ml.

For prevention:

SC route: 40 mg/kg bodyweight (2 ml/15 kg) to be administered once

The dose volume given at any one injection site should not exceed 10 ml.

The injection should only be given in the neck.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Pigs

Meat and offal: 18 days

Cattle

Meat and offal: by IM (at 20 mg/kg bodyweight, twice): 30 days

by SC (at 40 mg/kg bodyweight, once): 44 days

Milk: Not permitted for use in lactating animals producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

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

Once broached, use by

11. SPECIAL STORAGE CONDITIONS

Not applicable.

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

Disposal: read package leaflet.

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.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr Alderton
Towcester
Northamptonshire
NN12 7LS

16. MARKETING AUTHORISATION NUMBER

Vm 08007/4123

17. MANUFACTURER'S BATCH NUMBER
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Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label of 50 ml vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

KEFLORIL 300 mg/ml Solution for injection for cattle and pigs
Florfenicol

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Florfenicol.....300 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

50 ml.

4. ROUTE OF ADMINISTRATION

Pigs: IM
Cattle: IM or SC

5. WITHDRAWAL PERIOD

Pigs

Meat and offal: 18 days

Cattle

Meat and offal: by IM (at 20 mg/kg bodyweight, twice): 30 days
by SC (at 40 mg/kg bodyweight, once): 44 days

Milk: Not permitted for use in lactating animals producing milk for human consumption.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}

Shelf-life after first broaching the vial: 28 days.

Once broached, use by

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET FOR:

KEFLORIL 300 mg/ml Solution for injection for cattle and pigs

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

Marketing authorisation holder <and manufacturer responsible for batch release>:

Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr Alderton
Towcester
Northamptonshire
NN12 7LS

Manufacturer responsible for batch release:

VETOQUINOL
MAGNY-VERNOIS
F-70200 LURE
FRANCE

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

KEFLORIL 300 mg/ml Solution for injection for cattle and pigs
Florfenicol

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

Each ml contains:

Active substance: Florfenicol 300 mg/ml

Solution for injection.

Light yellow to yellow, clear viscous liquid

4. INDICATION(S)

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

Cattle: diseases caused by florfenicol susceptible bacteria.

Preventive and therapeutic treatment of respiratory tract infections in cattle due to *Mannheimia haemolytica*, *Pasteurella multocida* and *Histophilus somni*. The presence of the disease in the herd should be established before preventive treatment.

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

Pigs

Commonly observed adverse effects are transient diarrhoea and/or peri-anal and rectal erythema/ oedema which may affect 50% of the animals. These effects can be observed for one week.

Transient swelling lasting up to 5 days may be observed at the site of injection. Inflammatory lesions at the injection site may be seen up to 28 days.

Cattle

A decrease in food consumption and transient softening of the faeces may occur during the treatment period. The treated animals recover quickly and completely upon termination of treatment.

Administration of the product by the intramuscular route may cause swelling at the injection site which may persist for 14 days. Inflammation at the injection site may persist up to 32 days after administration.

Administration of the product by the subcutaneous route may cause swelling and inflammation at the injection site which may persist at least for 41 days.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle and pigs.

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

Pigs

15 mg/kg bodyweight (1 ml per 20 kg) by intramuscular injection into the neck muscle twice at

48-hour intervals using a dry, sterile 16-gauge needle.

The volume administered per injection site should not exceed 3 ml.

It is recommended to treat animals in the early stages of disease and to evaluate the response to treatment within 48 hours after the second injection.

If clinical signs of respiratory disease persist 48 hours after the last injection, treatment should be changed using another formulation or another antibiotic and continued until clinical signs have resolved.

Cattle

For treatment:

IM route: 20 mg/kg bodyweight (1 ml/15 kg) to be administered twice 48 hours apart using a 16 gauge needle.

SC route: 40 mg/kg bodyweight (2 ml/15 kg) to be administered once only using a 16 gauge needle. The dose volume given at any one injection site should not exceed 10 ml.

The injection should only be given in the neck.

For prevention:

SC route: 40 mg/kg bodyweight (2 ml/15 kg) to be administered once only using a 16 gauge needle. The dose volume given at any one injection site should not exceed 10 ml.

The injection should only be given in the neck.

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.

9. ADVICE ON CORRECT ADMINISTRATION

None

10. WITHDRAWAL PERIOD

Pigs

Meat and offal: 18 days

Cattle

Meat and offal: by IM (at 20 mg/kg bodyweight, twice): 30 days
by SC (at 40 mg/kg bodyweight, once): 44 days

Milk: Not permitted for use in lactating animals producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

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

Shelf-life after first-opening the container: 28 days.

12. SPECIAL WARNING(S)

Special warnings for each target species:

None

Special precautions for use in animals

Swab the stopper before removing each dose. Use a dry, sterile syringe and needle. Do not use in piglets of less than 2 kg.

Use of 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 product is used.

Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the florfenicol and may decrease the effectiveness of treatment with other antimicrobials, due to the potential for cross-resistance. Use a suitable draw-off needle or automatic dosing syringe to avoid excessive puncturing of the closure.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

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.

Do not use the product in known cases of sensitivity to propylene glycol and polyethylene glycols.

Avoid direct contact with skin, eyes or mouth.

In case of accidental spillage of the solution onto skin, wash off immediately with soap and water.

In case of accidental contact with eyes, rinse immediately with plenty of water.

Use during pregnancy, lactation or lay

Studies in laboratory animals have not revealed any evidence of embryo- or foetotoxic potential for florfenicol.

Pigs: the safety of the product in sows during pregnancy and lactation has not been demonstrated. Use of the product during pregnancy and lactation is therefore not recommended.

Cattle: the effect of florfenicol on bovine reproductive performance and pregnancy 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:

None Known

Overdose (symptoms, emergency procedures, antidotes):

Pigs

after administration of 3 times the recommended dose or more a reduction in feeding, hydration and weight gain has been observed.

After administration of 5 times the recommended dose or more vomiting has also been noted.

Cattle

No other symptoms than those mentioned in section 4.6 are expected.

Incompatibilities

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

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

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Presentation

50, 100 and 250 ml Type I amber glass bottle closed with a bromobutyl rubber stopper and aluminium seal.

1 bottle (50 ml) in cardboard box.

1 bottle (100 ml) in cardboard box.

1 bottle (250 ml) in cardboard box.

Not all pack sizes may be marketed.

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

Approved: 11 September 2018

