LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box for the 20, 50, 100, 250 and 500 mL vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NUFLOR Swine 300 mg/mL Solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 mL solution contains:
Florfenicol 300.00 mg/mL

3. PHARMACEUTICAL FORM

Solution for injection
Clear, light yellow to straw-colored, somewhat viscous solution, free from foreign matter solution for injection

4. PACKAGE SIZE

Carton box containing one 20 mL vial
Carton box containing one 50 mL vial
Carton box containing one 100 mL vial
Carton box containing one 250 mL vial
Carton box containing one 500 mL vial

5. TARGET SPECIES

Pigs.

6. INDICATION(S)

Not applicable for the outer package.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular injection. Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal: 18 days

9. SPECIAL WARNING(S), IF NECESSARY

Care should be taken to avoid accidental self-injection. Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached,/opened, use by 28 days

11. SPECIAL STORAGE CONDITIONS

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

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

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

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 REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands
(may deviate in some countries)

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label for the 100, 250 and 500 mL vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NUFLOR Swine 300 mg/mL Solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 mL solution contains:
Florfenicol 300.00 mg

3. PHARMACEUTICAL FORM

Solution for injection
Clear, light yellow to straw-colored, somewhat viscous solution, free from foreign matter
Solution for injection

4. PACKAGE SIZE

100 mL
250 mL
500 mL

5. TARGET SPECIES

Pigs.

6. INDICATION(S)

Not applicable for the outer package.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular injection. Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal: 18 days

9. SPECIAL WARNING(S), IF NECESSARY

Care should be taken to avoid accidental self-injection. Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached,/opened, use by 28 days

11. SPECIAL STORAGE CONDITIONS

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

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

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

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 REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands
(may deviate in some countries)

16. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label for the 20 and 50 mL vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NUFLOR Swine 300 mg/mL Solution for injection
Florfenicol

2. QUANTITY OF THE ACTIVE SUBSTANCE

1 mL solution contains:
Florfenicol 300.00 mg

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

20 mL
50 mL

4. ROUTE(S) OF ADMINISTRATION

Intramuscular injection.

5. WITHDRAWAL PERIOD

<Withdrawal period:> *[Not applicable for MRP/DCP]*

6. BATCH NUMBER

<Batch> <Lot> <BN> {number}

7. EXPIRY DATE

EXP {month/year}
Once broached,/opened, use by 28 days

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

NUFLOR Swine 300 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:

Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands
(may deviate in some countries)

Manufacturer for the batch release:

Schering-Plough Sante Animale
La Grindoliere, Zone Artisanale
49500 Segré
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

NUFLOR Swine 300 mg/mL Solution for injection

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

1 mL solution contains:
Florfenicol 300.00 mg

4. INDICATION(S)

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

5. CONTRAINDICATIONS

Do not administer to boars intended for breeding.
Do not administer in cases of previous allergic reactions to florfenicol.
Do not use in piglets of less than 2 kg.
See section 4.7

6. ADVERSE REACTIONS

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.

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

7. TARGET SPECIES

Pigs

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

15 mg/kg bodyweight (1 mL per 20 kg) by intramuscular injection into the neck muscle twice at 48 hour intervals using a 16-gauge needle. Do not use in piglets of less than 2 kg.

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.

9. ADVICE ON CORRECT ADMINISTRATION

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

Wipe the stopper before removing each dose. Use a dry, sterile syringe and needle.

Do not broach the vial more than 25 times.

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

10. WITHDRAWAL PERIOD

Meat and offal*: 18 days
* The withdrawal period is calculated from the last administration of the drug. It should be noted that whatever the withdrawal period no food of animal origin can be given to humans during the period of treatment.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Do not store above 25°C
Do not refrigerate.
Protect from frost.
Do not use after the expiry date which is stated on the label and carton.
Shelf life after first broaching the immediate packaging: 28 days

12. SPECIAL WARNING(S)

Care should be taken to avoid accidental self-injection.
Do not use in piglets of less than 2 kg.
The safety of the product in sows during pregnancy and lactation has not been demonstrated. Use of the product during pregnancy and lactation is not therefore recommended.
The product should be used in conjunction with susceptibility testing and take into account official and local antimicrobial policies.
Do not use the product in known cases of sensitivity to propylene glycol and polyethylene glycols.
After administration of overdoses, a reduction in feeding, hydration and weight gain as well as vomiting has been observed.

Do not mix the product with other 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 disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2009

15. OTHER INFORMATION

Not all pack sizes may be marketed.