PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Shotaflor 300 mg/ml solution for injection for pigs
Florfenicol

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Active substance:

Florfenicol……300 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml
100 ml
250 ml

5. TARGET SPECIES

Pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
The injection should only be given intramuscularly in the neck.
Wipe the stopper before removing each dose. Use a dry, sterile syringe and 16-gauge needle.
Not more than 3 ml should be administered at any one injection site.

8. WITHDRAWAL PERIOD

Withdrawal period:
Meat and offal: 18 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
Care should be taken to avoid accidental self-injection. Read package leaflet for full user safety warnings

10. EXPIRY DATE

EXP:
Shelf life after first opening the immediate container: 28 days.
Once opened, use by:

11. SPECIAL STORAGE CONDITIONS

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 be 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

Virbac S.A.
1ère avenue
2065 m L.I.D.
06516 Carros Cedex
France

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch :

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Shotaflor 300 mg/ml solution for injection for pigs
Florfenicol

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Active substance:

Florfenicol……300 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml
100 ml
250 ml

5. TARGET SPECIES

Pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
The injection should only be given intramuscularly in the neck.
Wipe the stopper before removing each dose. Use a dry, sterile syringe and 16-gauge needle.
Not more than 3 ml should be administered at any one injection site.

8. WITHDRAWAL PERIOD

Withdrawal period:
Meat and offal: 18 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
Care should be taken to avoid accidental self-injection. Read package leaflet for full user safety warnings.

10. EXPIRY DATE

EXP:
Shelf-life after first opening the immediate container: 28 days
Once opened, use by:

11. SPECIAL STORAGE CONDITIONS

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

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

Virbac S.A.
1ère avenue
2065 m L.I.D.
06516 Carros Cedex
France

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch :

PACKAGE LEAFLET

SHOTAFLOR 300 mg/ml solution for injection for pigs
Florfenicol

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

Virbac S.A.
1ère avenue
2065 m L.I.D.
06516 Carros Cedex
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

SHOTAFLOR 300 mg/ml solution for injection for pigs
Florfenicol

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

Each ml contains:

Active substance:

Florfenicol……300 mg

4. INDICATION(S)

Treatment of acute outbreaks of 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 use in case of hypersensitivity to the active substance or to any of the excipients.
See also section 12.
Do not use in case of resistance to the active substance.

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 hours interval using a dry, sterile 16-gauge needle.
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 injection should only be given in the neck.
Wipe the stopper before removing each dose. Use a dry, sterile syringe and 16-gauge needle.
Not more than 3 ml should be administered at any one injection site.

10. WITHDRAWAL PERIOD

Meat and offal: 18 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
This veterinary medicinal product does not require any special storage conditions.
Do not use after the expiry date stated on the label.
Shelf-life after first opening the container: 28 days.
When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package insert, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label and carton.

12. SPECIAL WARNINGS

For animal treatment only.
Do not exceed the recommended dose.
Treatment should not be repeated if an allergic reaction occurs.
Only administer by the routes outlined under points 8 and 9.
Do not use in piglets of less than 2 kg. Do not use the product in known cases of sensitivity to propylene glycol and polyethylene glycols.

Use a suitable draw-off needle or automatic dosing syringe to avoid excessive puncturing of the closures.
The product should be used in conjunction with susceptibility testing and take into account official and local antimicrobial policies.
Use of the 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 amfenicols, due to the potential for cross resistance.
The effect of the product in sows during pregnancy and lactation has not been demonstrated so the use of the product during pregnancy and lactation is not recommended.
After administration of at 3 times the recommended dose or more a reduction in feeding, hydration and weight gain was observed. After administration of 5 times the recommended dose or more vomiting has also been noted.
In the absence of incompatibility studies, this veterinary medicinal product should not be mixed with other veterinary medicinal products.

User warnings
Care should be taken to avoid accidental self-injection.
In the case of self-injection, seek medical advice and show the label to the doctor.
Do not use the product in known cases of sensitivity to florfenicol, propylene glycol and/or polyethylene glycols.
In case of accidental contact with eyes, rinse immediately with plenty of water.

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 be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Pack sizes:
50 ml
100 ml
250 ml

Not all pack sizes may be marketed.