PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Shotaflor 300 mg/ml solution for injection for cattle
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

For cattle.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
For intramuscular and subcutaneous use.
The injection should only be given in the neck.

8. WITHDRAWAL PERIOD

Withdrawal period:
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.

User warnings:
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 cattle
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

For cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
For intramuscular and subcutaneous use.
The injection should only be given in the neck.

8. WITHDRAWAL PERIOD

Withdrawal period:
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.

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 cattle
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 cattle
Florfenicol

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

Each ml of a light yellow to yellow, clear liquid contains:

Florfenicol……300 mg

4. INDICATION(S)

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 use in adult bulls intended for breeding purposes.
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

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.
In very rare cases, anaphylactic shocks have been reported in cattle.

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

7. TARGET SPECIES

Cattle.

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

For treatment:
IM route: 20 mg/kg bodyweight (1 ml/15 kg) to be administered twice 48 hours apart.
SC route: 40 mg/kg bodyweight (2 ml/15 kg) to be administered once only.
Intramuscular and subcutaneous injection.

For prevention:
SC route: 40 mg/kg bodyweight (2 ml/15 kg) to be administered once only.
Subcutaneous injection.

9. ADVICE ON CORRECT ADMINISTRATION

The injection should only be given in the neck.
Swab septum before removing each dose. Use a dry sterile 16 gauge needle and syringe.
The dose volume given at any one injection site should not exceed 10 ml.
To ensure a correct dosage body weight should be determined as accurately as possible to avoid under dosing.

10. WITHDRAWAL PERIOD

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 reach and sight of children.

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

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

Do not use after the expiry date stated on the label.

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 WARNING(S)

For animal treatment only.
Do not exceed the recommended dose.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.
Only administer by the routes outlined under point 8 and 9.
The product should be used in conjunction with susceptibility testing. Official and local antimicrobial policies should be taken into account.
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 florfenicol on bovine reproductive performance and pregnancy has not been assessed so it should only be used according to the benefit/risk assessment by your vet.
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 accidental 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 MATERIAL, 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

30/6/2010

15. OTHER INFORMATION

Pack sizes:
50 ml
100 ml
250 ml

Not all pack sizes may be marketed.