IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007

(S.I. No. 786 of 2007)

VPA:**10988/074/001**
Case No: 7004461

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

Virbac S.A.

Virbac 1, 1 ere Avenue, **2065 M - L.I.D., BP 27, 06516**, **Carros Cedex**, **France**

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Shotaflor 300mg/ml solution for injection for cattle

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in Part 2 of the said Schedule.

This authorisation,unless previously revoked, shall continue in force from **04/12/2009** to **03/12/2014**.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

SHOTAFLOR 300 mg/ml solution for injection for cattle
Florfenicol

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance

Florfenicol 300 mg

Excipients:
For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection
A light yellow to yellow, clear, viscous liquid.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle

4.2 Indications for use, specifying the target species

Diseases caused by florfenicol susceptible bacteria:
therapeutic treatment of respiratory tract infections in cattle due to *Mannheimia haemolytica, Pasteurella multocida* and *Histophilus somni.*

4.3 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.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Swab septum before removing each dose. Use a dry, sterile syringe and needle.
The product should be used in conjunction with susceptibility testing and take into account official and local antimicrobial policies**.**

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

Care should be taken to avoid accidental self-injection.

4.6 Adverse reactions (frequency and seriousness)

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 persists for 14 days. Inflammation at the injection site may persist up to 32 days after administration.

4.7 Use during pregnancy, lactation or lay

Studies in laboratory animals have not revealed 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 accordingly to the benefit/risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

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

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

None.

4.11 Withdrawal Period(s)

Meat and offal: 30 days

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

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, ATCVet code: QJ01BA90

5.1 Pharmacodynamic properties

Florfenicol is a synthetic broad spectrum antibiotic effective against most Gram-positive and Gram-negative bacteria isolated from domestic animals. Florfenicol acts by inhibiting protein synthesis at the ribosomal level and is bacteriostatic. Laboratory tests have shown that florfenicol is active against the most commonly isolated bacterial pathogens involved in bovine respiratory disease which include *Mannheimia haemolytica, Pasteurella multocida, and Histophilus somni*
Florfenicol is considered to be a bacteriostatic agent, but *in vitro* studies of florfenicol demonstrate bactericidal activity against *Mannheimia haemolytica, Pasteurella multocida* and *Histophilus somni*

Acquired resistance to florfenicol is mediated by efflux pump resistance associated with a *floR* gene. Such resistance has not yet been identified in the target pathogens except for *Pasteurella multocida*. Cross resistance with chloramphenicol can occur. Resistance to florfenicol and other antimicrobials has been identified in the food-borne pathogen *Salmonella typhimurium.*

5.2 Pharmacokinetic properties

Intramuscular administration at the recommended dose of 20 mg/kg maintains efficacious blood levels in cattle for 48 hours. Maximum mean plasma concentration (Cmax) of 3.86 µg/ml occurs at 5 hours (Tmax), after dosing. The mean plasma concentration 24 hours after dosing was 1.56 µg/ml.

The harmonic mean elimination half life was 18.8 hours.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dimethyl sulfoxide
Propylene glycol
Macrogol 400

6.2 Incompatibilities

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

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years
Shelf-life after first opening the immediate container: 28 days

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

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.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10988/074/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

4th December 2009

10 DATE OF REVISION OF THE TEXT