SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Shotaflor 300 mg/ml solution for injection for pigs
Florfenicol

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Florfenicol……300 mg

Excipient(s):

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

Pigs

4.2 Indications for use, specifying the target species

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

4.3 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 4.7.
Do not use in case of resistance to the active substance.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Wipe the stopper before removing each dose. Use a dry, sterile syringe and 16-gauge needle.
Do not use in piglets of less than 2 kg.
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.

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 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.

4.6 Adverse reactions (frequency and seriousness)

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.

4.7 Use during pregnancy, lactation or lay

Studies in laboratory animals have not revealed any evidence of embryo- or foeto-toxic potential for florfenicol. However, 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.

4.8 Interaction with other medicinal products and other forms of interaction

Not investigated.

4.9 Amounts to be administered and administration route

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.

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

In swine 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.

4.11 Withdrawal period(s)

Meat and offal: 18 days

5. PHARMACOLOGICAL PROPERTIES

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

5.1 Pharmacodynamic properties

Florfenicol is a broad-spectrum synthetic antibiotic active against most Gram-positive and Gram-negative bacteria isolated from domestic animals. Florfenicol acts by inhibition of protein synthesis at the ribosomal level and is bacteriostatic. However, bactericidal activity has been demonstrated *in-vitro* against *Actinobacillus pleuropneumoniae* and *Pasteurella multocida*.
In-vitro testing has shown that florfenicol is active against the bacterial pathogens most commonly isolated in respiratory diseases in pigs, including *Actinobacillus pleuropneumoniae* and *Pasteurella multocida*.

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.

5.2 Pharmacokinetic particulars

After a single intramuscular administration of the recommended dose of 15 mg/kg maximum plasma concentrations of 2.08 µg/ml were reached after 2 hours.
The harmonic mean elimination half life was 10.37 hours.
After administration to pigs by the intramuscular route, florfenicol is rapidly excreted, primarily in urine. The florfenicol is extensively metabolised.
Serum concentrations persist above 1 µg/ml for 12 to 24 hours following IM administration. Florfenicol concentrations achieved in lung tissue reflect plasma concentrations, with a lung: plasma concentration ratio of approximately 1.

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 packaging: 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 product or waste materials derived from the use of such products, if appropriate

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 LID
06516 Carros Cedex
France

8. MARKETING AUTHORISATION NUMBER

Vm 05653/4144

9. DATE OF FIRST AUTHORISATION

05 February 2008

10. DATE OF REVISION OF THE TEXT

September 2013

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable

APPROVED T. NASH **19/09/13**