Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Florvetol 300 mg/ml solution for injection for swine.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains
Active ingredient:
Florfenicol 300.00 mg

Excipients:
For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for Injection.
Clear, light yellow to straw-coloured, somewhat viscous solution, free from foreign matter.

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs.

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

Do not use in adult boars intended for breeding purposes.
Do not us in the case of a known hypersensitivity to the active substance or to any other ingredients of the product.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animal
Do not use in piglets of less than 2 kg.
Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

Special precautions to be taken by the person administering the medicinal product to animals
Care should be taken to avoid accidental self-injection.
Do not use the product in known cases of sensitivity to propylene glycol and polyethylene glycols.

Other precautions
None.

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

No data available.

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 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.

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 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
* 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.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterial for systemic use (Amphenicols)
ATC Vet 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*.

5.2 Pharmacokinetic properties

In pigs intravenously administered florfenicol had a mean plasma clearance rate of 5.2 ml/min/kg and a mean volume of distribution at equilibrium of 948 ml/kg. The mean terminal half-life is 2.2 hours.

After initial intramuscular administration of florfenicol, maximum serum concentrations of between 3.8 and 13.6 microgram/ml are reached after 1.4 hours and the concentrations deplete with a terminal mean half-life of 3.6 hours. After a second intramuscular administration, maximum serum concentrations of between 3.7 and 3.8 microgram/ml are reached after 1.8 hours. Florfenicol concentrations achieved in lung tissue reflect plasma concentrations, with a lung:plasma concentration ratio of approximately 1.

After administration to pigs by the intramuscular route, florfenicol is rapidly excreted, primarily in urine. The florfenicol is extensively metabolised.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

N-Methyl-2-Pyrrolidone
Propylene Glycol (E1520)
Macrogol 300

6.2 Incompatibilities

Do not mix the product with other 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.
Discard unused material.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Pack Sizes
20, 50, 100, 250 and 500 ml colourless Type I glass vials. The type I glass vials are closed with rubber stops.
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 material derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Schering-Plough Limited
Shire Park
Welwyn Garden City
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10277/092/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

24th September 2010

10 DATE OF REVISION OF THE TEXT