

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Nuflor 40 mg/g oral powder for pigs.
Florfenicol.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1g powder contains:

Active substance:

Florfenicol	40	mg
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Excipients:

Propylene Glycol	10	mg
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Ground Limestone	qs to 1	g
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For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral Powder.

White to off white, free flowing powder with red and/or black grains dispersed throughout.

4 CLINICAL PARTICULARS

4.1 Target Species

(Pigs) Fattening pigs.

4.2 Indications for use, specifying the target species

For the treatment of swine respiratory disease in individual pigs due to *Pasteurella multocida* susceptible to florfenicol.

4.3 Contraindications

Do not use in boars intended for breeding purposes.

Do not administer in cases of previous allergic reactions to florfenicol.

4.4 Special warnings for each target species

The treated pigs should be placed under special observation. On each of the five days of treatment, untreated food should not be given until the full daily amount of medicated feed has been ingested by the pigs. If there is no significant improvement after 3 treatment days, the diagnosis should be reviewed and if necessary the treatment should be changed.

Animals showing a decreased appetite and/or a poor general condition should be treated by the parenteral route.

4.5 Special precautions for use

Special precautions for use in animals

The product should be used in conjunction with susceptibility testing and take into account official and local antimicrobial policies.

This product contains ground limestone, which can lead to a decrease in food consumption and to a phosphorus calcium imbalance in feed intake. Therefore the calcium content of the final food shall be considered.

Treatment should not exceed 5 days.

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

Skin sensitisation may occur

Avoid skin contact.

Do not handle this product in case of known sensitisation to propylene glycol.

Handle this product with care to avoid exposure during incorporation of the powder into feed and administration of feed to animals, taking all recommended precautions.

Wear either a disposable half-mask respirator conforming to European standard EN 149 or a non-disposable respirator to European Standard EN 140 with a filter to EN 143, chemically resistant gloves, protective coveralls and goggles while incorporating the powder into feed.

Wear gloves and do not smoke, eat, or drink when handling the product or medicated feed.

Wash hands thoroughly with soap and water after use of the product or medicated feed

Rinse thoroughly with water in case of exposure.

If you develop symptoms following exposure such as skin rash, you should seek medical advice and show this information to the doctor.

Other precautions

Manure from treated pigs should be stored for one month prior to spreading and incorporating into land.

4.6 Adverse reactions (frequency and seriousness)

Commonly observed adverse effects are diarrhoea, perianal inflammation and rectal eversion. These effects are transient, resolving on cessation of treatment. Increased serum calcium may also be observed.

4.7 Use during pregnancy, lactation or lay

The safety of the product during pregnancy and lactation has not been studied in sows. Use of the product during pregnancy and lactation is therefore not recommended.

Do not use in breeding boars because toxicity studies in rats have shown adverse effects on the male reproductive system: See section 4.3 contraindications.

4.8 Interaction with other medicinal products and other forms of interaction

None known

4.9 Amounts to be administered and administration route

For use in individual pigs.

For use in feed. The product is recommended for use with non-pelleted feed.

Dosage:

The dosage is 10 mg of florfenicol (corresponding to 250 mg Nuflor 40 mg/g powder) per kg of body weight per day mixed in a portion of the daily feed ration on 5 consecutive days.

In order to ensure correct dosing and to prevent underdosing, the body weight shall be calculated as precisely as possible. The necessary amount of the product shall be weighed on a calibrated scale.

The correct dosage can be calculated as follows:

250 mg Nuflor 40 mg/g powder X body weight of the pig (kg)
per kg bodyweight and day

Special care has to be taken that the total dose is ingested.

The powder should be mixed into some of the feed to ensure it is thoroughly distributed. This mixture must be administered before the actual feed. When doing so it is recommended that the amount of Nuflor 40 mg/g powder calculated for the animal is mixed with feed in such a way that a maximum concentration of 500 mg florfenicol/kg feed is not exceeded.

Higher concentrations may adversely affect the taste and therefore lead to a reduction in food intake.

In cases of severe disease or inappetence the animals should be treated by the parenteral route.

For treatment of groups of pigs, use an appropriate premix incorporated into medicated feedingstuff by an authorised feed manufacturer

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

In the event of overdose, a reduction in food and water consumption, together with a decrease in bodyweight may be observed. There may be an increase in refused feed and an increase in serum calcium

4.11 Withdrawal Period(s)

Meat and offal: 14 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Antibiotic, member of the phenicol family

ATC vet code: QJ01BA90

5.1 Pharmacodynamic properties

Florfenicol is a broad-spectrum synthetic antibiotic in the phenicol group that is 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 *Pasteurella multocida* when florfenicol is present at concentrations above the MIC for 4 to 12 hours.

In-vitro testing has shown that florfenicol is active against the bacterial pathogens most commonly isolated in respiratory diseases in pigs, including *Pasteurella multocida*.

A total of 193 *Pasteurella multocida* isolates from the respiratory tracts of swine were collected between 2002 and 2003 in France, Spain, Greece, Germany, the United Kingdom and Belgium.

The Minimal Inhibitory Concentration (MIC) of florfenicol against the target pathogen ranges from 0.25 to 1 µg/ml with a MIC₉₀ of 0.5 µg/ml.

The only mechanisms of chloramphenicol resistance that are known to have significant clinical relevance are CAT-mediated inactivation and efflux-pump resistance. Of these, only some of the efflux mediated resistance would also confer resistance to florfenicol and thus have the potential to be affected by florfenicol use in animals.

5.2 Pharmacokinetic properties

After administration to pigs by gavage at 10 mg/kg under experimental conditions, absorption of florfenicol was variable but peak serum concentrations of approximately 5 µg/ml were reached approximately 3 hours after dosing. The terminal half-life was between 3 and 4 hours. After a single treatment the serum concentrations of florfenicol remained above 1 µg/ml for 12 to 18 hours.

After absorption and distribution, florfenicol is extensively metabolised by pigs and rapidly eliminated, primarily in urine and the faeces in a ratio of 3:1.

A fraction is secreted unchanged, the rest is metabolised to 5 metabolites.

After parenteral dosing of florfenicol to pigs, it has been shown that lung concentrations are similar to serum concentrations.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene Glycol
Ground Limestone

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years

Shelf life after first opening the immediate packaging: 3 months

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

LDPE/paper sealed sachet containing 250g or 1 kg powder.

LDPE/HDPE/paper/HDPE sealed sachet containing 3 kg powder.

Not all pack sizes may be marketed.

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

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Ltd.
Magna Drive,
Magna Business Park,
Citywest Road,
Dublin 24,
Ireland.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/265/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

21st August 2009

10 DATE OF REVISION OF THE TEXT

June 2012