



FLORXIN[®] 20 FG ORAL POWDER 20%W/W

Composition : Florfenicol 20% w/w (equivalent to 200 mg/g)

Product Description : White to off white powder.

Pharmacodynamics : 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.

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

Pharmacokinetics : After administration of 10 mg/kg b.w. to pigs under experimental conditions, mean maximal serum concentrations of approximately 7.4 µg/ml were reached within 1.5 hours after dosing. The terminal half-life was between approximately 2 and 4 hours. After a single treatment the serum concentrations of florfenicol remained above 1 µg/ml for 6 to 12 hours. Florfenicol is well absorbed when administered orally and following distribution it is rapidly eliminated in the urine and faeces in a ratio of 3:1. A fraction is excreted unchanged and the rest is metabolised into 5 major metabolites. After parenteral dosing of florfenicol to pigs, it has been shown that lung concentrations are similar to serum concentrations.

Indication : For swine. For the treatment of respiratory disease due to *Pasteurella multocida* and other microorganism susceptible to florfenicol.

Dosage and Administration:

To be mixed in feed.

10 mg of florfenicol per kg body weight (bw) per day mixed in a portion of the daily feed ration on 5 consecutive days.

Inclusion rate: 2kg of Florxin[®] 20FG per ton of feed .

Contraindication:

Do not use in boars intended for breeding purposes.

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

Warning & Precaution:

Special precautions for use in animals:

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.

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, 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 take the package leaflet or the label with you.

Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products:

Drug containers and any residual contents should be disposed of safely, according to the regulation in force.

Interaction with other medicaments : None known.

Statement on usage during pregnancy & lactation:

The safety of the veterinary medicinal product has not been established in sows during pregnancy and lactation.

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

Adverse Effect: 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.

Overdose and Treatment:

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.

Storage Condition: Store in cool and dry place, below 30°C.

Withdrawal Period: Meat : 14 days

Packing: 25 kg

FOR VETERINARY USE ONLY

Registration holder and manufactured by:



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Date of revision: January 2020
5LFLORX3-25K/04/JAN20

W10cm H14cm

LABEL CODE:	VERSION	COLORS
5LFLORX3-25K PRODUCT: FLORXIN 20 FG ORAL POWDER 20%W/W PACK SIZE: 25 KG COUNTRY: MY DIMENSIONS: cm = 10 x 14	Version: 4 MMM/YY: JAN 20	<div style="background-color: black; color: white; padding: 5px; text-align: center; width: 50px; margin: 0 auto;">Black</div> <p>! Please use the official PANTONE® (P) matching system for an accurate color representation.</p>

Marketing approval:	Regulatory approval:	GMP approval:
COMPLETE NAME: DATE + SIGNATURE:	COMPLETE NAME: DATE + SIGNATURE:	COMPLETE NAME: DATE + SIGNATURE: