

EFENDAZOLE 8% w/w PIL
W10cm x H14cm



EFENDAZOLE® 8%W/W

Oral Powder

Composition :
Fenbendazole 8% w/w

Product Description :
A white powder, premix for medicated stuff.

Pharmacodynamics :
A broad spectrum anthelmintic for the treatment of pigs infected with mature and immature forms of nematodes of the gastro-intestinal tracts. Each 1 g of Efendazole® 8% Powder contains 0.08 g of the active ingredient fenbendazole. Benzimidazoles bind to nematode tubulin, a protein necessary for the formation and viability of microtubules. This occurs primarily in absorptive intestinal cells resulting in a complete absence of microtubules in the intestinal cells of the nematode, which means that these cells cannot absorb nutrients, a consequent reduction in glycogen and effective starvation of the parasites. Structural differences have been shown to exist between tubulin from mammalian and helminth sources, thus resulting in the preferential toxicity of fenbendazole to the helminth and not to the host. Fenbendazole may also inhibit energy production in helminthes by inhibition of glucose uptake and glycogen breakdown.

Pharmacokinetics :
After oral administration fenbendazole is only partially absorbed. Following absorption, fenbendazole is rapidly metabolised in the liver mainly to its sulphoxide (oxfendazole) and further to its sulphone (oxfendazole sulphone). Oxfendazole is the main component detected in plasma, accounting for about 2/3 of the total AUC (i.e the sum of the AUC for fenbendazole, oxfendazole and oxfendazole sulphone). Fenbendazole and its metabolites are distributed throughout the body, reaching highest concentrations in the liver. The elimination of fenbendazole and its metabolites occurs primarily via the faeces and to small extent in the urine.

Indication :
Efendazole® 8% Powder is a broad spectrum anthelmintic for the treatment of pigs infected with mature and immature forms of nematodes of the gastrointestinal:
Hyoststrongylus rubidus (Red Stomach worm), *Oesophagostomum sp.* (Nodular worms), *Ascaris suum* (Round worm) and *Trichuris suis* (Whipworm). Also effective in the control of *Metastrongylus apri* (Lungworm)
Efendazole® 8% Powder has an ovicidal effect on nematode eggs.

Dosage and Administration:
Administered orally, mixed with feed.
Pigs: 5mg fenbendazole per kg bodyweight. The product may be administered to pigs either as a single dose or by divided dose over 7 days. It may also be administered to sows over 14 days. For the treatment of infections with *Trichuris* and for control of *Metastrongylus apri* the dose of 5mg/kg should be divided and spread over 7 days.

Contraindication:
Do not use in animals with known hypersensitivity to the active ingredient.

Warning & Precaution:
Special warnings for each target species

As with other anthelmintics, veterinary advice should be sought on appropriate dosing programme and stock management to achieve adequate parasite control and reduce the likelihood of anthelmintic resistance developing. If the product does not achieve the desired clinical effect, other diseases, nutritional disturbances or anthelmintic resistance may be involved.

Special precautions for use in animals
When preparing medicated feed, to ensure thorough dispersion, a premix should be prepared first. Once mixed, this should then be incorporated with the remaining feed.

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

When handling or mixing, suitable dust extraction equipment and suitable protective equipment such as rubber gloves and filtering masks or 'Pureflo' helmet must be used. Wash hands after handling medicated feed stuff. Direct contact with skin should be kept to a minimum.

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

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

Interaction with other medicaments :
None known

Statement on usage during pregnancy & lactation:
Efendazole® 8% Powder can be safely used during pregnancy and lactation.

Adverse Effect:
None known

Overdose and Treatment:
Benzimidazoles have a wide safety margin.

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

Withdrawal Period:
Meat and offal : After 14 days of the last treatment.

Packing: 2.5 kg

Registration holder and manufactured by:



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5LEFEND3-2.5 03/JAN20

LABEL CODE:		VERSION	COLORS
5LEFEND3-2.5		Version: 3 MMM/YY: JAN 20	Black ⚠ Please use the official PANTONE® (P) matching system for an accurate color representation.
PRODUCT: EFENDAZOLE 8% W/W ORAL POWDER PACK SIZE: 2.5 KG COUNTRY: MY DIMENSIONS: cm = 10 X 14			
Marketing approval:		Regulatory approval:	GMP approval:
COMPLETE NAME:		COMPLETE NAME:	COMPLETE NAME:
DATE + SIGNATURE:		DATE + SIGNATURE:	DATE + SIGNATURE: