RHOTARSIN® 20 WSP

Powder for Oral Solution
20% w/w

Composition: Tylosin tartrate 24.5% w/w (equivalent to Tylosin 20% w/w).
Product Description: White to off white powder.
Pharmacodynamics: Tylosin is a macrolide antibiotic produced by a strain of *Streptomyces fradiae*. It exerts its antimicrobial effect by inhibiting protein synthesis of susceptible micro-organisms. The tylosin spectrum of activity includes Gram-positive bacteria including *Clostridium perfringens* and some Gram-negative strains such as *Pasteurella* and *Mycoplasma spp.* at concentrations of 16µg/ml or less.
Pharmacokinetics: Absorption: Tylosin reaches maximal blood levels between 1 and 3 hours after an oral dose. Minimal or no blood levels remain 24 hours after an oral dose. Distribution: After oral doses were given to pigs, tylosin was found in all tissues, between 30 minutes and two hours after administration, except for the brain and spinal cord. Biotransformation and Elimination: It has been shown that most of the material which is excreted is to be found in the faeces and consists of tylosin (factor A), relomycin (factor D) and dihydrodesmycosin.
Indication: For the control of *Mycoplasma synoviae*, airsacculitis caused by *Mycoplasma gallisepticum* in chickens and turkeys. Used as preventive measure to reduce level of infections following stress induced by live vaccination. As an aid in the control of outbreaks of necrotic enteritis in chickens caused by *Clostridium perfringens*. For prevention and control of enzootic pneumonia, and scours caused by organisms (e.g. *Lawsonia intracellularis*) sensitive to tylosin, in pigs. For the control of pneumonia in calves associated with mycoplasma and *Pasteurella multocida* sensitive to tylosin.
Dosage and Administration: For oral administration.
Recommendations for use in chickens and turkeys:
Rhotarsin® 20WSP is administered in the drinking water at a concentration of 2.5g per litre.
For control of necrotic enteritis caused by *Clostridium perfingens* in chicken, use at dose rate of 0.75g per litre water or equivalent to 150 ppm or 20-50 mg/kg bw for 5 days.

Recommendation for use in pigs :
Rhotarsin® 20WSP is administered in the drinking water to provide 25mg tylosin/kg bodyweight. This may normally be achieved by adding 1.25g per litre.

Recommendations for use in calves :
1g of tylosin activity per calves administered orally twice daily for 7 to 14 days. The tylosin tartrate may be incorporated into the milk or reconstituted milk replacer at the time of feeding.

To ensure a correct dosage, body weight should be determined as accurately as possible to avoid under-dosing. Recommended programmes

a) Chickens and turkeys
For preventative medication the following programmes are recommended:
As an aid to mycoplasmosis prevention in chickens:

Class of stock	Age	Rhotarsin® 20WSP at 2.5g per litre
Broiler	0-3 days	175g per 1000 birds
	4th week of life	175g per 1000 birds
Layers and replacement pullets	0-3 days	175g per 1000 birds
	4th week of life	175g per 1000 birds
	9-12th week of life	48 hours medication
	16-20th week of life	48 hours medication
Breeders	0-3 days	250g per 1000 birds
	4th week of life	400g per 1000 birds
	9th, 12th, 16th, 20th, 24th weeks of age	48 hours medication

As an aid to mycoplasmosis prevention in turkeys:

Class of stock	Age	Rhotarsin® 20WSP at 2.5g per litre
Table turkeys	0-5 days	62.5g per 100 birds
	4th week of life	37.5g per 100 birds

For treatment of mycoplasmosis:

Class of stock	Rhotarsin® 20WSP at 2.5g per litre
Broilers	24-72 hours medication
Layers and replacement pullets	48-72 hours medication
Turkeys	48-120 hours medication

As an aid in the control of necrotic enteritis:

Class of stock	Rhotarsin® 20WSP at 0.75g per litre
Broilers	5 days
Layers and replacement pullets	5 days

b) Pigs
A medicated solution of drinking water should generally be administered until 24 hours after scouring or respiratory symptoms have ceased, normally 3-10 days. The diagnosis should be reviewed if there is no response after 5 days of medication.
Rhotarsin® 20WSP requirements per tonne of pigs daily:

Disease Treatment	Rhotarsin® 20WSP required	Water consumption (l) approx
Enzootic pneumonia	125 g	100 litres
Lleitis	25 – 500 g	100 litres

c) Calves
One gram of tylosin activity should be incorporated in milk or milk replacer twice daily for each calf. This should be continued for 7-14 days dependent on response. The intake of medicated water depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of Rhotarsin® 20WSP has to be adjusted accordingly.

Contraindication: Do not leave or dispose the water containing tylosin tartrate where it may be accessible to other animals that are not under treatment or to wildlife.
Do not use in other cases of hypersensitivity to tylosin or other macrolides.

Warning & Precaution:
Special precautions for use in animals
Use of the product deviating from the instructions given in the package insert may increase the prevalence of bacteria resistant to tylosin and may decrease the effectiveness of treatment with other macrolides, lincosamides and streptogramin B due to the potential for cross resistance.

Special precautions to be taken by the person administering the medicinal product to animals
Tylosin may induce irritation. Macrolides, such as tylosin, may also cause hypersensitivity (allergy) following injection, inhalation, ingestion or contact with skin or eye. Hypersensitivity to tylosin may lead to cross reactions to other macrolides and vice versa. To avoid exposure during preparation of the medicated drinking water, wear overalls, safety glasses, impervious gloves and wear either a disposable half mask respirator. Wash hands after use.
In the event of accidental skin contact, wash thoroughly with soap and water. In case of accidental eye contact, flush the eyes with plenty of clean, running water. Do not handle the product if you are allergic to ingredients in the product. If you develop symptoms following exposure, such as skin rash, you should seek medical advice and show the physician this warning. Swelling of the face, lips and eyes or difficulty in breathing are more serious symptoms and require urgent medical attention.

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 material derived from such veterinary medicinal products should be disposed of in accordance with national requirements.

Interaction with other medicaments : None known.

Statement on usage during pregnancy & lactation: No adverse effects to tylosin have been seen in fertility, multi-generation or teratology studies.

Adverse Effect: None known.

Overdose and Treatment: There is no evidence of tylosin toxicity in animals, at dose rates of up to 1000 mg/kg.

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

Withdrawal Period:

Species	Indications	Withdrawal Period (days) Meat	Withdrawal Period (days) Egg
Chickens	Mycoplasma / respiratory disease	1	0
	Necrotic enteritis caused by *Clostridium perfringens*	0	0
Turkeys	For the control of chronic respiratory disease	0	N/A
Pigs	For the prevention and control of enzootic pneumonia, swine dysentery and other scours caused by organisms (eg *Lawsonia intracellularis*) sensitive to tylosin.	0	N/A
Calves	For the control of pneumonia associated with mycoplasmata and *Pasteurella multocida* sensitive to tylosin.	14	N/A

Packing: 1 kg.

Registration holder and manufactured by:

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Date of revision: November 2019
5LRHOTA3-01K 02/NOV19

LABEL CODE:	VERSION	COLORS
5LRHOTA3-01K		Black
PRODUCT: RHOTARSIN 20WSP POWDER FOR ORAL SOLUTION 20% W/W	**Version: 2**	
PACK SIZE : 1KG	**MMM/YY: NOV 19**	
COUNTRY: MY		
DIMENSIONS: cm = 11 x 21.5		! Please use the official PANTONE® (P) matching system for an accurate color representation.

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