

MEDI-COC 50 (Toltrazuril 5% Oral Suspension)

MEDI-COC 50 (Toltrazuril 5% Oral Suspension) appears to be a white color suspension.

Composition

Each ml contains

Toltrazuril	50mg
Sodium Benzoate (as Preservative)	2.1mg

Pharmacodynamic

Toltrazuril is a triazinon derivative. It acts against coccidia of the genus *Cystoisospora* and *Eimeria*. It is active against all intracellular development stages of coccidia of the merogony (asexual multiplication) and gamogony (sexual phase). All stages are destroyed, thus the mode of action is coccidiocidal.

Pharmacokinetic

Piglets:

After oral administration toltrazuril is slowly absorbed with a bioavailability of $\geq 70\%$. The main metabolite is characterised as toltrazuril sulfone. The elimination of toltrazuril is slow with a half-life elimination time around 3 days. The major route of excretion is via the faeces.

Calves:

After oral administration in cattle toltrazuril is slowly absorbed. The maximal plasma concentration ($C_{max} = 36.6$ mg/l) was observed between 24 and 48 hours (geometric mean 33.9 hours) following oral administration. The elimination of toltrazuril is slow with a terminal half-life time of approximately 2.5 days (64.2 hours). The main metabolite is characterised as toltrazuril sulfone. The major route of excretion is via the faeces.

Lambs:

After oral administration toltrazuril is slowly absorbed in mammals. The main metabolite is characterised as toltrazuril sulfone. The maximal plasma concentration ($C_{max} = 62$ mg/L) was observed 2 days following oral administration. The elimination of toltrazuril is slow with an elimination half-life time of approximately 9 days. The major route of excretion is via the faeces.

Indications

Piglets: For the prevention of clinical signs of coccidiosis in neonatal piglets on farms with a confirmed history of coccidiosis caused by *Cystoisospora suis*.

Calves: For the prevention of clinical signs of coccidiosis and reduction of coccidian shedding in housed calves replacing cows producing milk for human consumption (dairy cows) on farms with a confirmed history of coccidiosis caused by *Eimeria bovis* or *Eimeria zuernii*.

Lambs: For the prevention of clinical signs of coccidiosis and reduction of coccidian shedding in lambs on farms with a confirmed history of coccidiosis caused by *Eimeria crandallis* and *Eimeria ovinoidalis*.

Recommended Dosage

For oral use. The oral suspension must be shaken before use.

To ensure administration of a correct dose, body weight should be determined as accurately as possible.

To obtain maximum benefit, animals should be treated before the expected onset of clinical signs, i.e. in the prepatent period.

Piglets

Individual animal treatment.

Each piglet should be treated between days 3 - 5 of life with a single oral dose of 20 mg toltrazuril per kg body weight corresponding to 0.4 ml oral suspension per kg body weight.

Due to the small volumes required to treat individual piglets, use of dosing equipment with a dose accuracy of 0.1 ml is recommended.

To obtain maximum benefit, animals should be treated before the expected onset of clinical signs, i.e. in the prepatent period.

To alter the course of an established clinical coccidial infection, in individual animals already showing signs of diarrhoea, additional supportive therapy may be required.

Treatment during an outbreak will be of limited value to the individual piglet because of damage to the small intestine having already occurred.

Special precautions for use in animals

Not applicable.

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

People with known hypersensitivity to toltrazuril, or any of the excipients, should avoid contact with the veterinary medicinal product.

This product can cause skin and eye irritation.

Avoid skin and eye contact with the product.

In case of accidental exposure to the skin or eyes, wash the affected area thoroughly with plenty of water.

If irritation persists, seek medical advice and show the package leaflet or the label to the physician.

Do not eat, drink or smoke whilst using the product.

Other Precautions

The major metabolite of toltrazuril, toltrazuril sulfone (ponazuril), has been shown to be both persistent (half-life >1 year) and mobile in soil and to be toxic to plants.

For environmental reasons:

Calves: In order to prevent any adverse effects on plants and possible contamination of groundwater manure from treated calves must not be spread onto land without dilution with manure from untreated cows. Manure from treated calves must be diluted with at least 3 times the weight of manure from mature cows before it can be spread onto land.

Lambs kept throughout the whole life span indoors under an intensive rearing system must not be treated beyond the age of 6 weeks or body weight of more than 20 kg at treatment. Manure from these animals should only be applied to the same piece of land every third year.

Interactions with Other Medicaments

None known.

Use during pregnancy, lactation or lay

Not applicable.

Side effects

None known.

Overdose and Treatment

No signs of intolerance were reported in healthy piglets and calves after oral administration of a threefold overdose.

No signs of overdose have been observed in lamb safety studies with threefold overdose at a single treatment and twofold overdose treatment on 2 consecutive days.

Withdrawal Period (s)

Piglets

Meat and offal: 77 days

Calves

Meat and offal: 63 days

Not authorised for use in animals producing milk for human consumption.

Lambs

Treatment during an outbreak will be of limited value for the individual piglet because of damage to the small intestine having already occurred.

Calves

Each animal should be treated with a single oral dose of 15 mg toltrazuril/kg body weight corresponding to 3.0 ml oral suspension per 10 kg body weight. If animals are to be treated collectively rather than individually, reasonably homogeneous groups of the same breed and same or similar age should be set up, and all animals of a group should be dosed at the rate corresponding to the heaviest one.

Lambs

Each animal should be treated with a single oral dose of 20 mg toltrazuril/kg body weight corresponding to 0.4 ml oral suspension per kg body weight. If animals are to be treated collectively rather than individually, reasonably homogeneous groups should be set up, and all animals of a group should be dosed at the rate corresponding to the heaviest one.

Contraindication

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

For environmental reasons:

Do not use in calves weighing more than 80 kg bodyweight.

Do not use in fattening units such as veal or beef calves.

Warning and Precautions

Special warnings for each target species

As with any antiparasiticide frequent and repeated use of antiprotozoals from the same class may lead to the development of resistance.

It is recommended to treat all animals in a pen.

Hygienic measures may reduce the risk of coccidiosis. It is therefore recommended to improve concomitantly the hygienic conditions in the concerned facility, particularly with regard to dryness and cleanliness.

Meat and offal: 42 days

Not authorised for use in animals producing milk for human consumption.

Storage

Store below 30°C. Protect from heat and sunlight exposure.

Keep out of reach of children/ Jauhkan daripada kanak-kanak.

Unused veterinary medicinal products or residues thereof should be disposed of in accordance with local requirements.

Shelf life as packaged for Sale: 3 years.

Shelf life after first opening: 30 days.

Packaging 1L

Product Registration Holder/Distributed By

GNC Agritech Sdn Bhd

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Manufacturer

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