

Premix for medicated feeding stuff

STATEMENT OF ACTIVE SUBSTANCE:

Diclazuril – 5 g/kg

PRODUCT DESCRIPTION:

COXIRIL® 0.5% w/w Premix for medicated feeding stuff represents granules of off-white to beige colour intended for administration through feed of broiler chickens and growing turkeys.

PHARMACODYNAMICS:

Diclazuril, a benzeneacetonitrile derivative, is a synthetic compound of the triazinone family.

According to the anticoccidial properties of triazinones, diclazuril is active against intracellular development stages of coccidia, namely during schizogony and gametogony.

After diclazuril treatment, the first- and second-generation schizonts show extensive degenerative changes which are characterised by the loss of internal structure, the appearance of many intracytoplasmic vacuoles and incomplete merogony. Ultrastructural findings indicate that diclazuril treatment primarily affects the normal differentiation of the respective endogenous stages during parasite development. This leads to complete degeneration of schizonts and gamonts.

PHARMACOKINETICS:

Biotransformation of diclazuril in chicken and turkey is low and the major compound found in plasma, tissues, urine and feces is the parent substance. Although poorly absorbed, diclazuril is detectable in plasma soon after administration with a t_{max} of about 6 hours.

INDICATIONS FOR USE:

As an aid in the prevention of coccidiosis in:

- Broiler chickens caused by *Eimeria acervulina*, *E. maxima*, *E. mitis*, *E. brunetti*, *E. necatrix* and *E. tenella*
- Growing turkeys caused by *E. adenoeides*, *E. gallopavonis* and *E. meleagrimitis*

RECOMMENDED DOSE:Broiler chicken:

1 mg/kg (milligram per kilogram) (0.0001%) of complete feed

Growing turkeys:

1 mg/kg (milligram per kilogram) (0.0001%) of complete feed

DIRECTIONS FOR USE:

For oral administration through the feed.

Broiler chicken:

To achieve 0.0001% concentration of diclazuril in complete feed, mix 200 g of COXIRIL® 0.5% w/w Premix for medicated feeding stuff per tonne of complete feed resulting in a final concentration of 1 g diclazuril per tonne of feed

(1 ppm). Feed this medicated feed as the sole ration from one day of age up until slaughter.

Growing turkeys:

To achieve 0.0001% concentration of diclazuril in complete feed, mix 200 g of COXIRIL® 0.5% w/w Premix for medicated feeding stuff per tonne of complete feed resulting in a final concentration of 1 g diclazuril per tonne of feed

(1 ppm). Feed this medicated feed as the sole ration from one day of age to a maximum of 14 weeks of age.

MODE OF ADMINISTRATION:

For oral administration through the feed.

CONTRAINDICATIONS:

Do not use diclazuril medicated feed for the treatment of outbreaks of coccidiosis.

WARNINGS AND PRECAUTIONS:

Do not use diclazuril medicated feed for the treatment of outbreaks of coccidiosis.

If unexpected deaths occur, obtain an accurate diagnosis and follow veterinarian's or poultry pathologist's recommendations.

Do not use with pellet binding agents except Pel-Aid or Lignin Sulfonate (Premix and Supplement labels only.)

INTERACTIONS WITH OTHER MEDICAMENTS:

Do not use with pellet binding agents except Pel-Aid or Lignin Sulfonate (Premix and Supplement labels only.)

STATEMENT ON USAGE DURING PREGNANCY AND LACTATION:

Not for use in hens producing eggs for human food.

ADVERSE EFFECTS/UNDESIRABLE EFFECTS:

Not established.

OVERDOSE AND TREATMENT:

Feed containing COXIRIL® 0.5% w/w Premix for medicated feeding stuff (from 1 ppm to 25 ppm) is given to the chickens in the course of the whole fattening period (42 days) without changes in the appetite, feed weight gain and without toxicological symptoms.

INCOMPATIBILITIES:

None known.

WITHDRAWAL PERIODS:

Broilers and growing turkeys: 0 days.

STORAGE CONDITIONS:

Store below 30°C. Store in a dry place. Protect from direct sunlight. Store in the original container.

SHELF-LIFE:

Shelf-life after first opening of the container:

6 months when stored at temperature up to 30°C.

Shelf-life after reconstitution into feed:

3 months when stored at temperature up to 25°C.

PACKAGING AVAILABLE:

Polyethylene-lined paper bags of 20 kg.

MANUFACTURER:

BIOVET Joint Stock Company
39 Petar Rakov Street, 4550 Peshtera,
Bulgaria

MARKETING AUTHORIZATION HOLDER:

Pahang Pharmacy Sdn. Bhd. (10826-K)
Lot 5979 Jalan Teratai, 5½ Mile Off Jalan Meru,
41050 Klang, Selangor Darul Ehsan, Malaysia

DATE OF REVISION:

September, 2017.