TOTRAX ORAL SOLUTION
(Toltrazuril)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

TOTRAX ORAL SOLUTION

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml Contains:
Toltrazuril ……. 25mg

3. PHARMACEUTICAL FORM

Oral Solution.

4. CLINICAL INFORMATION

4.1. Target species

Broiler Chickens & Turkeys.

4.2. Indications for use specifying the target species

Broilers Treatment of coccidiosis caused by *Eimeria acervulina, Eimeria brunetti, Eimeria maxima, Eimeria necatrix, Eimeria tenella, Eimeria mitis*

Turkeys Treatment of coccidiosis caused by *Eimeria adenoides, Eimeria meleagrimitis*

4.3. Contraindications

Do not use in animals with known hypersensitivity to toltrazuril or to any of the excipients.
Do not use in chickens over 16 weeks of age.
Do not administer to animals producing eggs for human consumption.

4.4. Special warnings for each target species

Too frequent and repeated use of anticoccidials and underdosing due to underestimation of live weight may increase the risk of development of resistance and therefore lead to the ineffectiveness of the veterinary medicinal product.
In case of anticoccidial therapy, evaluate the efficacy of the product with a post-treatment coprological examination. If the results of this test show the development of resistance to toltrazuril, use anticoccidials belonging to another pharmacological class and with a different mechanism of action.

4.5. Special precautions for use

Special precautions for safe use in the target species:

Dilutions above the recommended limit (greater than 1:1,000) may cause precipitation of the product.
Medicated water should be prepared daily.

Special precautions to be taken by the person administering the product to animals:

- In case of contact with skin or eyes, rinse immediately with water. Do not eat, drink, or smoke while handling this product.
- Operators must wash their hands after using the product.
- In case of accidental contact, rinse thoroughly with soap and water.
- People with known hypersensitivity to toltrazuril should avoid contact with the veterinary medicinal product.

4.6. Adverse reactions (frequency and seriousness)

No notes.

4.7. Use during pregnancy and lactation or lay

Use prohibited in animals producing eggs intended for human consumption.

4.8. Interaction with other veterinary medicinal products and other forms of interaction

In turkeys, concomitant treatment with antibiotics may lead to a reduction in water intake. No other interactions with other drugs are known. Totrax does not interfere with the development of immunity against coccidiosis.

4.9. Dosage and administration route

Administration: orally with drinking water
Dosage: Totrax should be diluted in drinking water. Stir gently.

The recommended dose is 7 mg toltrazuril per kg body weight per day for 2 consecutive days, equivalent to 28 ml of Totrax 2.5% per 100 kg body weight/day for 2 consecutive days, to be administered continuously over a 24-hour period or in an amount of water corresponding to 8 hours of consumption.

Depending on the amount of water consumed, this dose corresponds, as a guideline, to 25 ppm toltrazuril (1 ml of Totrax 2.5% per litre of drinking water) in the case of continuous administration for 48 hours and to 75 ppm (3 ml of Totrax 2.5% per litre of drinking water) in the drinking water administered for 8 hours/day for 2 consecutive days.

The calculated dose must not be less than 7 mg of pa per kg body weight.

Treatment regimen: the duration of therapy is two days.

4.10. Overdose (symptoms, emergency procedures, antidotes), if necessary

If the recommended dose is exceeded, a reduction in water intake may occur.

4.11. Withdrawal period:

Meat and offal Chickens: 14 days
Turkeys: 28 days

Not indicated for use in birds producing or intended to produce eggs for human consumption. Do not use within 6 weeks of the start of the egg-laying period.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiprotozoal products.
ATC-vet code: **QP51BC01**

5.1. Pharmacodynamics properties

Toltrazuril is an anticoccidial belonging to the chemical group of symmetric triazinetriones. It induces changes in the fine structure of coccidial developmental stages, which are mainly due to swelling of the endoplasmic reticulum and Golgi apparatus, as well as abnormalities in the perinuclear space and disturbances in nuclear division. Toltrazuril leads to a reduction in enzymatic activity in the respiratory chain of the parasites.

5.2 Pharmacokinetic information

In poultry, once absorbed, the active substance is rapidly metabolized. The highest residue concentrations are found in the liver and kidney. The main metabolite has been identified as toltrazuril sulfone (marker residue). At the time of slaughter, this metabolite represents approximately 100% of the total residues in chickens and turkeys.

6. PHARMACEUTICAL INFORMATION

6.1 List of Excipients:

Triethanolamine
Polyethylene glycol

6.2 Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3. Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the container: use immediately in 28 days, do not store.

6.4. Special precautions for storage

Store below 25°C.
Protect from light and moisture.
Keep out of the reach of children.
To be used as directed by the registered veterinary practitioner only.

6.5. Nature and composition of primary conditioning

HDPE bottles with induction-sealed caps
Pack sizes: 100ml, 250ml, 500ml, and 1L

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF WASTE MATERIALS
UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS

Waste materials derived from the use of such products
Medicinal products should not be disposed of via wastewater or household waste.
Use return systems for unused veterinary medicinal products or waste materials derived from such products, in accordance with local requirements and national collection systems applicable to the veterinary medicinal product concerned.
Treated animals should be kept in shelters throughout the treatment period and their droppings should be collected and NOT used for soil fertilization.

7. MARKETING AUTHORISATION HOLDER

Nawan Laboratories (Pvt.) Ltd.
Plots No. 136-138, Sector-15,
Korangi Industrial Area, Karachi-74900, Pakistan.

8. MARKETING AUTHORISATION NUMBER

Reg. No.: 084983

9. DATE OF FIRST AUTHORISATION

Date of Reg: 08-09-2017

10. DATE OF REVISION OF THE TEXT

17-02-2025

MANUFACTURED BY:

NAWAN LABORATORIES (PVT) LTD. | 136, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan.