

**PACKAGE LABEL - LEAFLET**

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**Zuritol 25 mg/ml oral solution for poultry**

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holder and manufacturer:

LABORATORIOS CALIER, S.A.  
C/ Barcelonès, 26 (Pla del Ramassà)  
LES FRANQUESES DEL VALLÈS, (Barcelona)  
SPAIN

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Zuritol 25 mg/ml oral solution for poultry  
Toltrazuril

**3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)**

Toltrazuril 25 mg  
Clear colourless to brown solution

**4. INDICATION(S)**

Treatment of Coccidiosis in pullets and Broiler Breeders.

**5. CONTRAINDICATIONS**

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

**6. ADVERSE REACTIONS**

None known.

**7. TARGET SPECIES**

Chickens (pullets and breeders)

**8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION**

For oral administration (in drinking water).

The recommended dose rate is 7 mg per kg of body weight (equivalent to 28 ml of medicinal product per 100 kg of body weight or 1.4 ml of the product per liter of drinking water based on a water consumption of 1 liter per 5 kg body weight) daily given for 2 consecutive days, This medicinal product should be administered either continuously over 48 hours, or for one 8 hour period per day for 2 consecutive days

The total weight of the treated animals and the daily water consumption must be accurately calculated.

**9. ADVICE ON CORRECT ADMINISTRATION**

The consumption of water may vary depending in particular on the clinical condition, the ambient temperature, the lighting program, the drinking system used, the age and breed. If the water consumption is more or less than the above standards, the concentration of the medicinal product in the drinking water should be adjusted accordingly.

Use appropriate and properly calibrated dosing equipment. Medicated water should be the only drinking source.

The medicated water is only usable for 24 hours and should be made freshly every day.

Dilutions more concentrated than 3:1,000 (3 ml of product to 1 litre drinking water) may result in precipitation. Predilution is not recommended.

After the end of the medication period the water supply system should be cleaned appropriately to avoid intake of sub-therapeutic amounts of the active substance.

#### **10. WITHDRAWAL PERIOD**

Meat and offal: 16 days.

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

#### **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

Do not use after the expiry date stated on the label.

Shelf-life after dilution in drinking water: 24 hours

Shelf-life after first opening the immediate packaging: 3 months

Once broached/opened, use by ....

#### **12. SPECIAL WARNING(S)**

##### **Special warnings for each target species**

As with all anticoccidials, frequent and prolonged use of an antiprotozoal of the same class may result in the development of resistances.

##### **Special precautions for use in animals**

Good hygiene can reduce the risk of coccidiosis. It is therefore recommended any deficiencies in husbandry should be addressed in addition to treatment. Poultry houses should be kept clean and dry. It is recommended that all individuals in the group are treated. For best results, treatment should be initiated before the clinical signs of disease have spread throughout the whole group.

This veterinary medicinal product is a strongly alkaline solution and should not be administered undiluted.

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

This product is an alkaline solution-contact with skin and mucous membranes should be avoided. Personal protective equipment consisting of gloves and goggles should be worn when handling this product. Wash any splashes from skin or eyes immediately with water. In case of irritation of eyes or skin after exposure, seek medical advice immediately and show the package leaflet or the label to the physician.

People with known sensitivity to toltrazuril, or any excipient, should avoid contact with this product.

Do not eat, drink or smoke while handling the product.

##### **Overdose (symptoms, emergency procedures, antidotes):**

The first signs of intolerance such as reduced water intake were observed beyond 10 times the recommended dose.

##### **Incompatibilities**

Do not mix with other veterinary medicinal products.

#### **13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

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

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

**15. OTHER INFORMATION**

For animal treatment only - to be supplied only on veterinary prescription.

Marketing authorisation number(s):

Manufacturer's batch number:

Expiry date: EXP {month/year}

1 litre HDPE bottles

5 litre HDPE bottles

Not all pack sizes may be marketed