PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

1L and 5L container

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TOLTRA-K 25 mg/ml Solution for use in Drinking Water for chickens and turkeys

2. COMPOSITION

Each ml contains:

Active substance:
Toltrazuril 25 mg

Clear colourless to brown solution.

3. PACKAGE SIZE

1L
5L

4. TARGET SPECIES

Chicken (pullets and chickens for reproduction) and turkey

5. INDICATIONS FOR USE

Indications for use
For the treatment of coccidiosis caused by:
Chicken (pullets and chickens for reproduction): *Eimeria acervulina, E. brunetti, E. maxima, E. necatrix and E. tenella*.
Turkey: *Eimeria adenoides, E. meleagrimitis*.

6. CONTRAINDICATIONS

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

7. SPECIAL WARNINGS

Special warnings

Special warnings:
Hygiene measures help to reduce the risk of coccidiosis. It is therefore recommended that attention be paid during treatment to hygiene in confinement buildings, particularly in terms of general cleanliness and moisture reduction.
It is recommended to treat all animals in a pen. For best results, treatment should be initiated before the clinical signs of disease have spread throughout the whole group.

Special precautions for safe use in the target species:
The veterinary medicinal product is a strongly alkaline solution and should not be administered undiluted.
As with any antiparasiticide, frequent and prolonged use of an antiprotozoal of the same class of active substance and underdosing due to underestimation of the live weight may result in the development of resistances.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This veterinary medicinal 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.
Do not ingest. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Interactions with other medicinal products and other forms of interaction:
Combination of the product with antibiotics may result in reduced water intake in turkeys. The concomitant administration of other substances to the drinking water should be avoided.

Overdose:
The first signs of intolerance such as reduced water intake were observed beyond 3-5 times the recommended dose.

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

8. ADVERSE EVENTS

Adverse events

Chicken (pullets and chickens for reproduction) and turkey: None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder, the local representative of the marketing authorisation holder using the contact details on this label, or via your national reporting system {national system details}.

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration
In drinking water use

The recommended dose rate is 7 mg toltrazuril per kg of body weight (equivalent to 28 ml of medicinal product per 100 kg of body weight) daily given for 2 consecutive days

The treatment is recommended to be given either continuously over 24 h or alternatively at a treatment duration of 8 hours per day.

To ensure a correct dosage, body weight should be determined as accurately as possible.

The intake of medicated water depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of toltrazuril may need to be adjusted accordingly.

Considering continuous treatment over 24 hours the following calculation should be made for providing the required amount of veterinary medicinal product in ml per litre drinking water:

0.28 ml veterinary medicinal product per kg bodyweight per day	X	mean body weight (kg) of animals to be treated	= x ml veterinary medicinal product per litre drinking water
mean water consumption (l) per animal (24 hours)			

Total demand of veterinary medicinal product per day (24 hours):
The calculated volume (x ml veterinary medicinal product per litre) should then be multiplied with the total daily water consumption (l) for the 24 hour period.

Considering a treatment duration of 8 hours per day the following calculation should be made for providing the required amount of veterinary medicinal product in ml per litre drinking water:

0.28 ml veterinary medicinal product per kg bodyweight per day	X	mean body weight (kg) of animals to be treated	= x ml veterinary medicinal product per litre drinking water
mean water consumption (l) per animal per 8 hours			

Total demand of veterinary medicinal product for a treatment duration of 8 hours:
The calculated volume (x ml veterinary medicinal product per litre) should then be multiplied with the water consumption (l) for the 8 hour period.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration
The veterinary medicinal product should be dissolved in drinking water (gentle mixing) before use.
The use of acidic water may cause precipitation of the active substance at recommended doses. The solution should be prepared daily.
At doses ranging from 1 ml to 3 ml of the veterinary medicinal product per litre of drinking water, the solubility is ensured over the treatment period. Dilutions more concentrated than 3:1,000 (3 ml of product to 1 litre drinking water) may result in precipitation.
Because of potential solubility issue, the administration via header tanks should be avoided.
The use of suitably calibrated weighing equipment is recommended if part of containers is used.

Sufficient access to the system of water supply should be available for the animals to be treated to ensure adequate water consumption. No other source of drinking water should be available during the medication period. In free range husbandry systems animals should be kept in the stable during treatment.

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.

11. WITHDRAWAL PERIODS

Withdrawal periods

Chicken:	Meat and offal:	18 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.
Turkey:	Meat and offal:	16 days

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.
Do not store above 30ºC.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products
Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 31223/3000

Pack sizes
Bottle of 1 L
Bottle of 5 L
Not all pack sizes may be marketed.

16. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

17. CONTACT DETAILS

Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

LABORATORIOS KARIZOO, S.A
Polígono Industrial La Borda
Mas Pujades 11-12
08140 – CALDES DE MONTBUI
Barcelona
Spain
Telf: +34 93 865 41 48
Email: pharmacovigilance@alivira.es

18. OTHER INFORMATION

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}

Shelf-life after first opening the immediate packaging: 3 months
Shelf-life after dilution or reconstitution according to directions: 24 hours
Once opened, use by …

21. BATCH NUMBER

Lot {number}

Gavin Hall

Approved: 12 June 2024