SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Toltrazuril 25 mg

Excipient:

Qualitative composition of excipients and other constituents
Trolamine
Macrogol 200

Clear colourless to brown solution.

3. CLINICAL INFORMATION

3.1 Target species

Chicken (pullets and chickens for reproduction) and turkey

3.2 Indications for use for each target species

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*.

3.3 Contraindications

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

3.4 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.

3.5 Special precautions for use

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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

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

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details..

3.7 Use during pregnancy, lactation or lay

Not applicable (see section 3.12)

3.8 Interaction 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.

3.9 Administration routes and dosage

In drinkwing 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 mg/ml X per kg bodyweight per day	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 X bodyweight per day	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.

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP 51AJ01

4.2 Pharmacodynamics

Toltrazuril is an anticoccidial of the triazinetrione group, active against Eimeria *spp*, Its activity affects the intracellular development stages of the parasitewithout affecting the extracellular stages of the parasites.
At parasite level, toltrazuril decreases the enzymatic activity of the respiratory chain, causing inflammation of the endoplasmic reticulum and Golgi apparatus, perinuclear space modifications and alteration of division of the nucleus.

4.3 Pharmacokinetics

In chickens and turkeys, totrazuril is absorbed at rate of at least 50%. Distribution is higher in liver and kidney. The active substance is rapidly metabolised and the main metabolite is characterised as a toltrazuril sulfone.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 21months
Shelf-life after first opening the immediate packaging: 3 months
Shelf-life after dilution or reconstitution according to directions: 24 hours

5.3 Special precautions for storage

Do not store above 30ºC.

5.4 Nature and composition of immediate packaging

Bottle of white high-density polyethylene bottles, closed with a high-density polyethylene screw cap with low-density polyethylene induction sealing.

Package sizes:
Bottle of 1 L
Bottle of 5 L

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS KARIZOO, S.A.

7. MARKETING AUTHORISATION NUMBER

Vm 31223/3000

8. DATE OF FIRST AUTHORISATION

05 November 2012

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

June 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

Gavin Hall

Approved: 12 June 2024