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

One ml contains:

Active substance:
Toltrazuril 25 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for use in drinking water
Clear colourless to brown solution

4. CLINICAL PARTICULARS

4.1 Target species

Chicken (pullets and breeders) and turkey

4.2 Indications for use, specifying the target species

For the treatment of coccidiosis caused by:
Chicken (pullets and breeders): *Eimeria acervulina, E. brunetti, E. maxima, E. necatrix and E. tenella*.
Turkeys: *Eimeria adenoides, E. meleagrimitis*.

4.3 Contraindications

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

4.4 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.

4.5 Special precautions for use

Special precautions for use in animals

Good hygiene can reduce the risk of coccidiosis. It is therefore recommended that 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.
The 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.

4.6 Adverse reactions (frequency and seriousness)

None known

4.7 Use during pregnancy, lactation or lay

Not applicable (see section 4.11)

4.8 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.

4.9 Amounts to be administered and administration route

Administration: Oral route (in drinking water)

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.

For the preparation of medicated water the body weight of the animals to be treated and their actual daily water consumption should be taken into account. Consumption may vary depending on factors like species, age, state of health, breed and husbandry system (e.g. different temperature, different light regimes).

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 TOLTRA-K 25 mg/ml per kg bodyweight per day	X mean body weight (kg) of animals to be treated	= x ml TOLTRA-K 25 mg/ml per litre drinking water
mean water consumption (l) per animal (24 hours)		

Total demand of TOLTRA-K 25 mg/ml per day (24 hours):
The calculated volume (x ml TOLTRA-K 25 mg/ml 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 TOLTRA-K 25 mg/ml per kg bodyweight per day	X mean body weight (kg) of animals to be treated	= x ml TOLTRA-K 25 mg/ml per litre drinking water
mean water consumption (l) per animal per 8 hours		

Total demand of TOLTRA-K 25 mg/ml for a treatment duration of 8 hours:
The calculated volume (x ml TOLTRA-K 25 mg/ml 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.

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

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

4.11 Withdrawal period(s)

Chicken

Meat and offal: 18 days
Eggs: not authorised for use in laying birds producing eggs for human consumption. Do not use within 4 weeks of the onset of laying.

Turkey

Meat and offal: 16 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiprotozoals. Triazines.
ATCvet code: QP 51AJ01

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Trolamine
Macrogol 200

6.2 Incompatibilities

In absence of compatibility studies the product cannot be mixed with other veterinary products.

6.3 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

6.4. Special precautions for storage

Do not store above 30ºC.

6.5 Nature and composition of immediate packaging

The product is packaged in white high-density polyethylene containers of 1 L and 5 L. Containers are closed with a high-density polyethylene screw cap with low-density polyethylene induction sealing.
Not all pack sizes may be marketed.

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

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

7. MARKETING AUTHORISATION HOLDER

Laboratorios Karizoo, S.A.
Polígono Industrial La Borda
Mas Pujades, 11-12
08140 – Caldes De Montbui (Barcelona)
Spain

8. MARKETING AUTHORISATION NUMBER

Vm 31223/4002

9. DATE OF FIRST AUTHORISATION

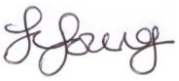
05 November 2013

10. DATE OF REVISION OF THE TEXT

November 2013

PROHIBITION OF SALE, SUPPLY AND/OR USE

For animal treatment only.
To be supplied only on veterinary prescription

Approved:  **05/11/2013**