ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

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

1L and 5L containers

1. Name and address of the marketing authorisation holder and of the marketing authorisation holder responsible for batch release, if different

Marketing authorisation holder and manufacturer responsible for batch release:
Laboratorios Karizoo S.A.
Polígono Industrial La Borda
Mas Pujades, 11-12
08140 Caldes de Montbui (Barcelona)
Spain

2. Name of the veterinary medicinal product

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

3. Statement of the active substance(s) and other ingredients

One ml contains:

Active substance:
Toltrazuril 25 mg

4. Pharmaceutical form

Solution for use in drinking water
Clear colourless to brown solution.

5. Package size

1L
5L

6. Indication(s)

For the treatment of coccidiosis caused by:

Chicken (pullets and chickens for reproduction): *Eimeria acervulina*, *E. brunetti*, *E. maxima*, *E. necatrix*, *E. tenella*.
Turkey: *Eimeria adenoides, E. meleagrimitis*.

7. Contraindications

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

8. Adverse reactions

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

Alternatively you can report via your national reporting system {national system details}.

9. Target species

Chicken (pullets and chickens for reproduction) and turkey.

10. Dosage for each species, route(s) and method of administration

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.

In order to ensure administration of a correct dose, accurately determine the bodyweight of the animals.

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:

$$\frac{\text{0.28 ml TOLTRA-K 25 mg/ml per kg bodyweight per day} \times \text{mean body weight (kg) of animals to be treated}}{\text{mean water consumption (l) per animal (24 hours)}} = \text{x ml TOLTRA-K 25 mg/ml per litre drinking water}$$

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
mean water consumption (l) per animal per 8 hours		= x ml TOLTRA-K 25 mg/ml per litre drinking water

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.

11. 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.

12. Withdrawal period(s)

Withdrawal period

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.

13. Special storage precautions

Do not store above 30ºC.
When the container is opened for the first time, using the in-use shelf-life which is specified on this label, the date on which any product remaining in the

container should be discarded should be worked out. This discard date should be written in the space provided.

14. Special warning(s)

Special warnings for each target species
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 use in animals
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 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.

Pregnancy and lactation:
Not applicable

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.

Overdose (symptoms, emergency procedures, antidotes):
The first signs of intolerance such as reduced water intake were observed beyond 3- 5 times the recommended dose.

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

15. 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 product should be disposed of in accordance with local requirements.

16. Date on which the label was last approved

17. Other information

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

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

18. The words "For animal treatment only" and conditions or restrictions regarding supply and use, if applicable

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

[PL]
Wyłącznie dla zwierząt - Wydawany z przepisu lekarza – Rp.
Do podawania pod nadzorem lekarza weterynarii
[ES]
Uso veterinario-Medicamento sujeto a prescripción veterinaria.
Administración bajo control o supervisión del veterinario.

19. The words "Keep out of the sight and reach of children"

Keep out of the sight and reach of children.

20. Expiry date

EXP:
Shelf-life after first opening the immediate packaging: 3 months
Once broached,/opened, use by…
Shelf-life after dilution or reconstitution according to directions: 24 hours
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
[PL]
Termin ważności (EXP)

21. Marketing authorisation number

Vm 31223/4002

22. Manufacturer's batch number

Batch {number}
[PL]
Nr serii (Lot)

Approved: 28 July 2023