<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>
<PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE>

1 L and 5L container

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TOLCOX 25 mg/ml Solution for use in Drinking Water for chickens and turkeys.
Toltrazuril

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One ml contains:

Active substance:
Toltrazuril 25 mg

3. PHARMACEUTICAL FORM

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

4. PACKAGE SIZE

1L
5L

5. TARGET SPECIES

Chicken (pullets and breeders) and turkey.

6. INDICATION(S)

For the treatment of coccidiosis caused by:

Chicken (pullets and breeders): *Eimeria acervulina, E. brunetti, E. maxima, E. necatrix, E. tenella*.
Turkeys: *Eimeria adenoides, E. meleagrimitis*.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

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

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

8. WITHDRAWAL PERIOD

Chicken:

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

Turkey:

	Meat and offal:	16 days

9. SPECIAL WARNING(S), IF NECESSARY

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
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

Use during pregnancy, lactation or lay:
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), if necessary:
The first signs of intolerance such as reduced water intake were observed beyond 3- 5 times the recommended dose.

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

10. 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
[PL]
Termin ważności (EXP)

11. SPECIAL STORAGE CONDITIONS

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.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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.

13. 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

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children

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

Marketing authorisation holder:
VETPHARMA ANIMAL HEALTH, S.L
Les Corts, 23
08028 Barcelona
SPAIN

Manufacturer for the batch release
LABORATORIOS KARIZOO, S.A.
Polígono Industrial La Borda
Mas Pujades, 11-12
08140 – CALDES DE MONTBUI (Barcelona)
SPAIN

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch
[PL]
Nr serii (Lot)

18. OTHER INFORMATION

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

Adverse reactions
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

Not all pack sizes may be marketed

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

Date on which the package label-leaflet was last approved: