[Version 9.1,11/2024]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baycox 25 mg/ml, solution for use in drinking water for chickens and turkeys (AT, BE, DE, FR, IE, LU, NL, PT, UK(NI))

Baycox PT 25", 25 mg/ml solution for use in drinking water for broilers and turkeys (IT)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml solution contains:

Active substance:
Toltrazuril 25 mg

Excipients:

Qualitative composition of excipients and other constituents
Macrogol 200
Trolamine

Colourless to brown solution.

3. CLINICAL INFORMATION

3.1 Target species

Chickens (broilers, pullets and breeders) and turkeys.

3.2 Indications for use for each target species

For the treatment of coccidiosis in chickens and turkeys, caused by infections with various species of *Eimeria*:

Chickens: *E. acervulina*, *E. brunetti*, *E. maxima*, *E. mitis*, *E. necatrix*, *E. tenella*.
Turkeys: *E. adenoides* and *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

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 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:

As with all anticoccidials, frequent and prolonged use of an antiprotozoal of the same class may result in the development of resistances. It is important to keep to the recommended dose in order to minimise the risk of resistance.
If resistance is present it should be considered to use other antiprotozoal from another class/mechanism of action.
This veterinary medicinal product should not be used together with feed additives/or other veterinary medicinal products that might interfere with the efficacy of the product, like "coccidiostats" and "histomonostats".

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:
People with known hypersensitivity to toltrazuril should avoid contact with the veterinary medicinal product.
The veterinary medicinal product is an alkaline solution.
Personal protective equipment consisting of synthetic rubber gloves should be worn when handling the veterinary medicinal product.
Contact with skin, mucous membranes and ingestion should be avoided.
In case of direct contact with the eyes or skin, wash immediately and thoroughly with water.
In case of accidental spillage onto skin or accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Do not eat, drink or smoke during use.
Wash hands after use.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Chickens (broilers, pullets and breeders) and turkeys: 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 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 veterinary medicinal 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 drinking water use. For oral administration.

To ensure a correct dosage, body weight (bw) of the treated animals and the daily water consumption should be determined as accurately as possible.

The recommended dose rate is 7 mg toltrazuril per kg bw per day (equivalent to 0.28 ml of veterinary medicinal product per kg bw per day). Treatment is carried out on two consecutive days.

The veterinary medicinal product should be administered continuously over 24 hours per day for 2 consecutive days.
In case an automatic dose dispenser is used the veterinary medicinal product should be administered for one period of 8 hours per day for 2 consecutive days.
Medicated drinking water should be refreshed every 24 hours.

The intake of medicated water depends on the clinical condition of the animals, such as the animal species, the age, state of health and intended use of the animals and the housing conditions (e.g. different ambient temperature, different lighting regime). In order to obtain the correct dosage, the concentration of toltrazuril may need to be adjusted accordingly.

In the case of continuous treatment over 24 hours, the required amount of veterinary medicinal product to be mixed into the drinking water for the animals to be treated is calculated according to the following formula:

Volume of veterinary medicinal product required per litre of drinking water:

$$\frac{\text{0.28 ml veterinary medicinal product per kg bw per day} \times \text{Average bw (kg) of the animals to be treated}}{\text{Average daily water intake (litres per animal)}} = \text{x ml veterinary medicinal product per litre of drinking water}$$

Total volume of veterinary medicinal product required per day (24 h):
The calculated volume (x ml veterinary medicinal product per litre) must be multiplied with the total consumption of drinking water (l) per day (24 h).

In the case of treatment for a period of 8 hours per day, the required amount of veterinary medicinal product to be mixed into the drinking water for the animals to be treated is calculated according to the following formula:

Volume of veterinary medicinal product required per litre of drinking water:

$$\frac{\text{0.28 ml veterinary medicinal product per kg bw per day} \times \text{Average bw (kg) of the animals to be treated}}{\text{Average 8 hours water intake (litres per animal)}} = \text{y ml veterinary medicinal product per litre of drinking water}$$

Total volume of veterinary medicinal product required for a treatment period of 8 hours:
The calculated volume (y ml veterinary medicinal product per litre) must be multiplied by the total consumption of drinking water (l) per 8-hour period.

The appropriate volume of the veterinary medicinal product must be added daily to the drinking water while stirring.

At doses ranging from 1 and 4 ml of the veterinary medicinal product per litre of drinking water, the solubility is guaranteed over the period of treatment.

In order to ensure that all the animals drink water evenly, sufficient space must be made available at the waterer. Free-range animals must be kept indoors during treatment.

After the end of the treatment, the watering system must be cleaned in an appropriate manner in order to prevent any exposure to residual subtherapeutic doses, particularly if liable to promote the development of resistance.

Predilution and the administration through a dosing pump (proportioner) are not recommended. Preferably use a bulk tank.

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

A reduction in drinking water intake may be the first sign of an overdose. This is observed only after an overdose with more than 10 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

Chickens:
Meat and offal: 16 days
Turkeys:
Meat and offal: 16 days

Eggs: 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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP51BC01

4.2 Pharmacodynamics

Toltrazuril is an anticoccidial of the triazinetrione group, active against *Eimeria* spp. Toltrazuril induces changes in the fine structure of the developmental stages of coccidia. These are caused primarily by swelling of the endoplasmic reticulum and of the Golgi apparatus, abnormal changes to the perinuclear space and disturbances in cell division. Toltrazuril causes a decrease in the activity of respiratory chain enzymes in the parasites.

4.3 Pharmacokinetics

After oral administration, toltrazuril undergoes at least 50% absorption in poultry. The highest concentrations are to be found in the liver and kidneys of the poultry. The active substance is broken down rapidly. The main metabolite is 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: 5 years
Shelf life after first opening the immediate packaging: 3 months

After a prolonged storage period, yellow to yellow-brown discoloration of the solution may occur, although this does not impair the quality of the veterinary medicinal product.

Shelf life after dilution or reconstitution according to directions: 24 hours.

5.3 Special precautions for storage

Do not store above 25 °C.

5.4 Nature and composition of immediate packaging

100 ml or 1000 ml white HDPE bottles closed with light green polypropylene screw cap with a red tamper evident seal.
5000 ml white HDPE canister with an aluminium sealing disc, closed with a black polyethylene screw cap and a yellow tamper evident seal.

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

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

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

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*).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX, 100 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baycox 25 mg/ml, solution for use in drinking water (AT, BE, DE, FR, IE, LU, NL, PT, UK(NI))

Baycox PT 25", 25 mg/ml solution for use in drinking water (IT)

2. STATEMENT OF ACTIVE SUBSTANCES

Active substance:
Toltrazuril 25 mg/ml

3. PACKAGE SIZE

100 ml

4. TARGET SPECIES

Chickens (broilers, pullets and breeders) and turkeys

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

In drinking water use.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal:
Chickens: 16 days
Turkeys: 16 days

Eggs: 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.

8. EXPIRY DATE

Exp. {mm/yyyy}
Shelf life after first opening the container: 3 months.
Once opened use by …
Once diluted use within 24 hours.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco [logo]

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

PLASTIC BOTTLE 100 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baycox 25 mg/ml, solution for use in drinking water (AT, BE, DE, FR, IE, LU, NL, PT, UK(NI))

Baycox PT 25", 25 mg/ml solution for use in drinking water (IT)

2. STATEMENT OF ACTIVE SUBSTANCES

Active substance:
Toltrazuril 25 mg/ml

3. TARGET SPECIES

Chickens (broilers, pullets and breeders) and turkeys

4. ROUTES OF ADMINISTRATION

In drinking water use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:

Meat and offal:
Chickens: 16 days
Turkeys: 16 days

Eggs: 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.

6. EXPIRY DATE

Exp. {mm/yyyy}
Shelf life after first opening the container: 3 months.
Once opened use by …
Once diluted use within 24 hours.

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco [logo]

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - <u>COMBINED LABEL AND PACKAGE LEAFLET</u>

1000 ml bottle, 5000 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baycox 25 mg/ml, solution for use in drinking water for chickens and turkeys (BE, FR, IE, LU UK(NI))

Baycox PT 25", 25 mg/ml solution for use in drinking water for broilers and turkeys (IT)

2. COMPOSITION

Active substance:
Toltrazuril 25 mg/ml

Colourless to brown solution.

3. PACKAGE SIZE

1000 ml
5000 ml

4. TARGET SPECIES

Chickens (broilers, pullets and breeders) and turkeys

5. INDICATIONS FOR USE

Indications for use
For the treatment of coccidiosis in chickens and turkeys, caused by infections with various species of *Eimeria*:

Chickens: *E. acervulina, E. brunetti, E. maxima, E. mitis, E. necatrix, E. tenella*.
Turkeys: *E. adenoides and 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

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 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:
As with all anticoccidials, frequent and prolonged use of an antiprotozoal of the same class may result in the development of resistances. It is important to keep to the recommended dose in order to minimise the risk of resistance.
If resistance is present it should be considered to use other antiprotozoal from another class/mechanism of action.
This veterinary medicinal product should not be used together with feed additives/or other veterinary medicinal products that might interfere with the efficacy of the product, like 'coccidiostats' and 'histomonostats.
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:
People with known hypersensitivity to toltrazuril should avoid contact with the veterinary medicinal product.
The veterinary medicinal product is an alkaline solution.
Personal protective equipment consisting of synthetic rubber gloves should be worn when handling the veterinary medicinal product.
Contact with skin, mucous membranes and ingestion should be avoided.
In case of direct contact with the eyes or skin, wash immediately and thoroughly with water.
In case of accidental spillage onto skin or accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Do not eat, drink or smoke during use.
Wash hands after use.

Laying birds:
Not applicable, see section "Withdrawal periods".

Interaction with other medicinal products and other forms of interaction:
Combination of the veterinary medicinal 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:
A reduction in drinking water intake may be the first sign of an overdose. This is observed only after an overdose with more than 10 times the recommended dose.

Special restrictions for use and special conditions for use:
Not applicable.

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

Chickens (broilers, pullets and breeders) and turkeys: 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 in 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 using the contact details on this label, or via your national reporting system:

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

Dosage for each species, routes and method of administration

In drinking water use. For oral administration.

To ensure a correct dosage, body weight (bw) of the treated animals and the daily water consumption should be determined as accurately as possible.

The recommended dose rate is 7 mg toltrazuril per kg bw per day (equivalent to 0.28 ml of veterinary medicinal product per kg bw per day). Treatment is carried out on two consecutive days.
The veterinary medicinal product should be administered continuously over 24 hours per day for 2 consecutive days.

In case an automatic dose dispenser is used the veterinary medicinal product should be administered for one period of 8 hours per day for 2 consecutive days.
Medicated drinking water should be refreshed every 24 hours.

The intake of medicated water depends on the clinical condition of the animals, such as the animal species, the age, state of health and intended use of the animals and the housing conditions (e.g. different ambient temperature, different lighting regime). In order to obtain the correct dosage, the concentration of toltrazuril may need to be adjusted accordingly.

In the case of continuous treatment over 24 hours, the required amount of veterinary medicinal product to be mixed into the drinking water for the animals to be treated is calculated according to the following formula:

Volume of veterinary medicinal product required per litre of drinking water:

$$\frac{\text{0.28 ml veterinary medicinal product per kg bw per day} \times \text{Average bw (kg) of the animals to be treated}}{\text{Average daily water intake (litres per animal)}} = \text{x ml veterinary medicinal product per litre of drinking water}$$

Total volume of veterinary medicinal product required per day (24 h):
The calculated volume (x ml veterinary medicinal product per litre) must be multiplied with the total consumption of drinking water (l) per day (24 h).

In the case of treatment for a period of 8 hours per day, the required amount of veterinary medicinal product to be mixed into the drinking water for the animals to be treated is calculated according to the following formula:

Volume of veterinary medicinal product required per litre of drinking water:

$$\frac{\text{0.28 ml veterinary medicinal product per kg bw per day} \times \text{Average bw (kg) of the animals to be treated}}{\text{Average 8 hours water intake (litres per animal)}} = \text{y ml veterinary medicinal product per litre of drinking water}$$

Total volume of veterinary medicinal product required for a treatment period of 8 hours:

The calculated volume (y ml veterinary medicinal product per litre) must be multiplied by the total consumption of drinking water (l) per 8-hour period.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

The appropriate volume of the veterinary medicinal product must be added daily to the drinking water while stirring.

At doses ranging from 1 and 4 ml of the veterinary medicinal product per litre of drinking water, the solubility is guaranteed over the period of treatment.

In order to ensure that all the animals drink water evenly, sufficient space must be made available at the waterer. Free-range animals must be kept indoors during treatment.

After the end of the treatment, the watering system must be cleaned in an appropriate manner in order to prevent any exposure to residual subtherapeutic doses, particularly if liable to promote the development of resistance.

Predilution and the administration through a dosing pump (proportioner) are not recommended. Preferably use a bulk tank.

11. WITHDRAWAL PERIODS

Withdrawal periods
Chickens:
Meat and offal: 16 days
Turkeys:
Meat and offal: 16 days

Eggs: 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.

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions
Keep out of the sight and reach of children.

Do not store above 25 °C.

Do not use this veterinary medicinal product after the expiry date which is stated on the container after Exp. The expiry date refers to the last day of that month.

After a prolonged storage period, yellow to yellow-brown discoloration of the solution may occur, although this does not impair the quality of the product.

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

Pack sizes
100 ml and 1000 ml white HDPE bottles closed with light green polypropylene screw cap with a red tamper evident seal.
5000 ml white HDPE canister with an aluminium sealing disc, closed with a black polyethylene screw cap and a yellow tamper evident seal.

Not all pack sizes may be marketed.

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised

{MM/YYYY}

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

17. CONTACT DETAILS

Contact details

Marketing authorisation holder <and contact details to report suspected adverse events>:

Manufacturer responsible for batch release:
KVP Pharma- und Veterinär Produkte GmbH
Projensdorfer Str. 324
D-24106 Kiel, Germany

<Local representatives <and contact details to report suspected adverse events>>:

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

18. OTHER INFORMATION

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}
Once diluted use within 24 hours.
Once opened, use by …
Shelf life after first opening the immediate packaging: 3 months

21. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Baycox 25 mg/ml, solution for use in drinking water for chickens and turkeys (AT, BE, DE, FR, IE, LU, NL, PT, UK(NI))

Baycox PT 25", 25 mg/ml solution for use in drinking water for broilers and turkeys (IT)

2. Composition

Each ml solution contains:

Active substance:
Toltrazuril 25 mg

Colourless to brown solution.

3. Target species

Chickens (broilers, pullets and breeders) and turkeys

4. Indications for use

For the treatment of coccidiosis in chickens and turkeys, caused by infections with various species of *Eimeria*:

Chickens: *E. acervulina, E. brunetti, E. maxima, E. mitis, E. necatrix, E. tenella*.
Turkeys: *E. adenoides and E. meleagrimitis*.

5. Contraindications

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

6. Special warnings

Special warnings:
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 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:
As with all anticoccidials, frequent and prolonged use of an antiprotozoal of the same class may result in the development of resistances. It is important to keep to the recommended dose in order to minimise the risk of resistance.
If resistance is present it should be considered to use other antiprotozoal from another class/mechanism of action.
This veterinary medicinal product should not be used together with feed additives/or other veterinary medicinal products that might interfere with the efficacy of the product, like ”coccidiostats” and “histomonostats”.

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:
People with known hypersensitivity to toltrazuril should avoid contact with the veterinary medicinal product.
The veterinary medicinal product is an alkaline solution.
Personal protective equipment consisting of synthetic rubber gloves should be worn when handling the veterinary medicinal product.
Contact with skin, mucous membranes and ingestion should be avoided.
In case of direct contact with the eyes or skin, wash immediately and thoroughly with water.
In case of accidental spillage onto skin or accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Do not eat, drink or smoke during use.
Wash hands after use.

Laying birds:
Not applicable, see section "Withdrawal periods".

Interaction with other medicinal products and other forms of interaction:
Combination of the veterinary medicinal 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:
A reduction in drinking water intake may be the first sign of an overdose. This is observed only after an overdose with more than 10 times the recommended dose.

Special restrictions for use and special conditions for use:
Not applicable.

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

7. Adverse events

Chickens (broilers, pullets and breeders) and turkeys: 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 in this package leaflet, or you think that the medicine has not worked, please contact, in first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:

8. Dosage for each species, routes and method of administration

In drinking water use. For oral administration.

To ensure a correct dosage, body weight (bw) of the treated animals and the daily water consumption should be determined as accurately as possible.

The recommended dose rate is 7 mg toltrazuril per kg bw per day (equivalent to 0.28 ml of veterinary medicinal product per kg bw per day). Treatment is carried out on two consecutive days.

The veterinary medicinal product should be administered continuously over 24 hours per day for 2 consecutive days.
In case an automatic dose dispenser is used the veterinary medicinal product should be administered for one period of 8 hours per day for 2 consecutive days.
Medicated drinking water should be refreshed every 24 hours.

The intake of medicated water depends on the clinical condition of the animals, such as the animal species, the age, state of health and intended use of the animals and the housing conditions (e.g. different ambient temperature, different lighting regime). In order to obtain the correct dosage, the concentration of toltrazuril may need to be adjusted accordingly.

In the case of continuous treatment over 24 hours, the required amount of veterinary medicinal product to be mixed into the drinking water for the animals to be treated is calculated according to the following formula:

Volume of veterinary medicinal product required per litre of drinking water:

$$\frac{\text{0.28 ml veterinary medicinal product per kg bw per day} \times \text{Average bw (kg) of the animals to be treated}}{\text{Average daily water intake (litres per animal)}} = \text{x ml veterinary medicinal product per litre of drinking water}$$

Total volume of veterinary medicinal product required per day (24 h):
The calculated volume (x ml veterinary medicinal product per litre) must be multiplied with the total consumption of drinking water (l) per day (24 h).

In the case of treatment for a period of 8 hours per day, the required amount of veterinary medicinal product to be mixed into the drinking water for the animals to be treated is calculated according to the following formula:

Volume of veterinary medicinal product required per litre of drinking water:

$$\frac{\text{0.28 ml veterinary medicinal product per kg bw per day} \times \text{Average bw (kg) of the animals to be treated}}{\text{Average 8 hours water intake (litres per animal)}} = \text{y ml veterinary medicinal product per litre of drinking water}$$

Total volume of veterinary medicinal product required for a treatment period of 8 hours:
The calculated volume (y ml veterinary medicinal product per litre) must be multiplied by the total consumption of drinking water (l) per 8-hour period.

9. Advice on correct administration

The appropriate volume of the veterinary medicinal product must be added daily to the drinking water while stirring.

At doses ranging from 1 and 4 ml of the veterinary medicinal product per litre of drinking water, the solubility is guaranteed over the period of treatment.

In order to ensure that all the animals drink water evenly, sufficient space must be made available at the waterer. Free-range animals must be kept indoors during treatment.

After the end of the treatment, the watering system must be cleaned in an appropriate manner in order to prevent any exposure to residual subtherapeutic doses, particularly if liable to promote the development of resistance.

Predilution and the administration through a dosing pump (proportioner) are not recommended. Preferably use a bulk tank.

10. Withdrawal periods

Chickens:
Meat and offal: 16 days
Turkeys:
Meat and offal: 16 days

Eggs: 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.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25 °C.

Shelf life after first opening the immediate packaging: 3 months

When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the carton should be discarded should be worked out. This discard date should be written in the space provided.

Do not use this veterinary medicinal product after the expiry date which is stated on the container after Exp. The expiry date refers to the last day of that month.

After a prolonged storage period, yellow to yellow-brown discoloration of the solution may occur, although this does not impair the quality of the veterinary medicinal product.

Once opened, use by …
Once diluted use medicated water within 24 hours, any water not consumed to be discarded.

12. 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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Pack sizes:
100 ml or 1000 ml white HDPE bottles closed with light green polypropylene screw cap with a red tamper evident seal.
5000 ml white HDPE canister with an aluminium sealing disc, closed with a black polyethylene screw cap and a yellow tamper evident seal.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

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

16. Contact details

Marketing authorisation holder <and contact details to report suspected adverse events>:

Manufacturer responsible for batch release:
KVP Pharma- und Veterinär Produkte GmbH
Projensdorfer Str. 324
D-24106 Kiel, Germany

<Local representatives <and contact details to report suspected adverse events>>:

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