Austrian
Federal Office for
Safety in Healthcare
BASG

# PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

**Baycox Direct 25 mg/ml, Lösung zum Eingeben über das Trinkwasser für Hühner und Puten**

**AT/V/0012/001**

**Last update**: 05/03/2024

**Modules 1-3 reflect the scientific discussion for the approval of Baycox Direct 25 mg/ml, Lösung zum Eingeben über das Trinkwasser für Hühner und Puten. The procedure was finalised on 18/06/2014. For information on changes after this date please refer to module 4.**

# MODULE 1

## PRODUCT SUMMARY

| | |
|---|---|
| EU procedure number | AT/V/0012/001/DC |
| Name, strength and pharmaceutical form | Baycox Direct 25 mg/ml, Lösung zum Eingeben über das Trinkwasser für Hühner und Puten |
| Applicant | Bayer Animal Health GmbH<br>51368 Leverkusen<br>Germany |
| Active substance(s) | TOLTRAZURIL |
| ATCvet code | QP51AJ01 |
| Target species | Chickens (broilers, pullets and breeders), turkey |
| Indication for use | For the treatment of coccidiosis in chickens and turkeys, caused by infections with various species of Eimeria:<br>Chickens: *E. acervulina, E. brunetti, E. maxima, E. mitis, E. necatrix, E. tenella*.<br>Turkeys: *E. adenoides and E. meleagrimitis*. |

# MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Veterinary Medicines Agencies website (http://www.HMA.eu).

# MODULE 3

**PUBLIC ASSESSMENT REPORT**

| | |
|---|---|
| Legal basis of original application | Generic application in accordance with Article 13 (1) of Directive 2001/82/EC as amended. |
| Reference medicinal product | Baycox 25 mg/ml, Lösung zum Eingeben für Huhn und Pute |
| Date of completion of the original <mutual recognition> <decentralised> procedure | 18/06/2014 |
| Date product first authorised in the Reference Member State (MRP only) | Not applicable |
| Concerned Member States for original procedure | BE, DE, FR, IE, IT, LU, NL, PT, UK |

## I. SCIENTIFIC OVERVIEW

The product is produced and controlled using validated methods and tests, which ensure the consistency of the product released on the market.

It has been shown that the product can be safely used in the target species; the slight reactions observed are indicated in the SPC (see 4.6 "adverse reactions").

The product is safe for the user, the consumer of foodstuffs from treated animals and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC (see 4.5 "Special precautions for use").

The efficacy of the product was demonstrated according to the claims made in the SPC.

The overall risk/benefit analysis is in favour of granting a marketing authorisation.

## II. QUALITY ASPECTS

### II.A Qualitative and quantitative particulars

The product contains:

Active substance: 25 mg/ml toltrazil (see 2. of SPC) and

excipient(s): macrogol 200 and trolamine, (see 6.1 of SPC).

Container/closure system: HDPE bottle closed with light green polypropylene screw cap with a red tamper evident seal. (see 6.5 of SPC).

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

## II.B Method of Preparation of the Product

The product is manufactured fully in accordance with the principles of good manufacturing practice at a licensed manufacturing site.

The product is manufactured in accordance with the European Pharmacopoeia and relevant European guidelines.

## II.C Control of Starting Materials

The active substance is toltrazuril. The active substance is manufactured in accordance with the principles of good manufacturing practice.

The active substance specification is considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification have been provided.

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

## II.D Control on intermediate products (pharmaceuticals)

Not applicable.

## II.E Control Tests on the Finished Product

The finished product specification controls the relevant parameters for the pharmaceutical form. The tests in the specification, and their limits, have been justified and are considered appropriate to adequately control the quality of the product.

Satisfactory validation data for the analytical methods have been provided.

Batch analytical data from the proposed production site<s> have been provided demonstrating compliance with the specification.

## II.F Stability

Stability data on the active substance has been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance when stored under the approved conditions.

Stability data on the finished product have been provided in accordance with applicable European guidelines, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.

The claim of stability after broaching is acceptable, for details see section 6.3 of SPC.

## II.G Other Information

### *Shelf life*

Shelf life of the veterinary medicinal product as packaged for sale: 5 years

### *In-use shelf life*

Shelf life after first opening the immediate packaging: 3 months

### *Special precautions for storage*

Do not store above 25°C.

## III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

Since the application is made in accordance with Article 13(1) of Directive 2001/82/EC, as amended, for a generic veterinary medicinal product, data on safety and residues are not required. The data submitted are in accordance with the requirements of the applicable European bioequivalence guideline.

## III.A Safety Testing

### *Pharmacological Studies*

As this is a generic application according to Article 13, and bioequivalence with the reference product has been demonstrated, results of pharmacodynamics and pharmacokinetics tests are not required.

### *Toxicological Studies*

As this is a generic application according to Article 13, and bioequivalence with the reference product has been demonstrated, results of toxicological tests are not required.

### *User Safety*

As this is a generic application according to Article 13, and bioequivalence with the reference product has been demonstrated, a detailed user safety assessment is not required. The safety warnings are the same as for the reference product.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

### *Environmental Risk Assessment*

The applicant provided a Phase I and Phase II environmental risk assessment (ERA) for toltrazuril and the metabolite toltrazuril sulfone in compliance with the relevant CVMP/VICH guidelines GL6 and GL38.

The results of the assessment for the terrestrial plants and groundwater compartments indicate that the product will not pose a risk to those compartments when used as recommended.

Warnings and precautions as listed on the product literature are adequate to ensure safety to the environment when the product is used as directed in the SPC.

# III.B Residues documentation

## *Residue Studies*

No residue depletion studies were conducted because, in accordance with the data requirements of the applicable European bioequivalence guideline, it was demonstrated that the product is a generic of Baycox 25 mg/ml, Lösung zum Eingeben für Huhn und Pute and that the residue depletion profile will be the same.

## *MRLs*

Maximum Residue Limits (MRLs) for the active substance toltrazuril is included in Table 1 of the Annex to Commission Regulation (EU) No 37/2010 as follows:

| **Pharmacologically active substance(s)** | **Marker residue** | **Animal species** | **MRLs (µg/kg)** | **Target tissues** |
|---|---|---|---|---|
| Toltrazuril | Toltrazuril sulfone | All mammalian food producing species | 100<br>150<br>500<br>250 | Muscle<br>Fat<br>Liver<br>Kidney |
| | | Poultry | 100<br>200<br>600<br>400 | Muscle<br>Skin and fat<br>Liver<br>Kidney |

The excipient macrogol 200 which is contained in the generic product is included in Table 1 of the Annex to Commission Regulation (EU) No 37/2010 as "No MRL required". The excipients trolamine and water for injection are "Out of Scope" of that Regulation.

## *Withdrawal Periods*

The withdrawal periods for the proposed product are the same as those of the reference product as follows:
Chickens:
Meat and offal: 16 days
Turkeys:
Meat and offal: 16 days
Eggs:
Not authorised for use in laying birds producing eggs for human consumption. Do not use within 4 weeks of onset of laying.

# IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13, and bioequivalence with the reference product has been demonstrated, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

## IV.A Pre-Clinical Studies

### *Pharmacology*

As this is a generic application according to Article 13, and bioequivalence with the reference product has been demonstrated, pharmacodynamic and pharmacokinetic studies are not required.

### *Tolerance in the Target Species of Animals*

As this is a generic application according to Article 13, and bioequivalence with the reference product has been demonstrated, tolerance studies are not required.

### *Resistance (if relevant – or delete)*

The bibliography / information provided suggests that the intended target pathogens are susceptible.

Adequate warnings and precautions appear on the product literature, for details see section 4.5 of SPC.

## IV.B Clinical Studies

### *Laboratory Trials*

As this is a generic application according to Article 13, and bioequivalence with the reference product has been demonstrated, laboratory studies are not required as they have already been presented for the reference product.

### *Field Trials*

As this is a generic application according to Article 13, and bioequivalence with the reference product has been demonstrated, field studies are not required as they have already been presented for the reference product.

The product is efficacious when used according to the SPC.

# V . OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the product is used in accordance with the Summary of Product Characteristics, the risk benefit profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.

# MODULE 4

## POST-AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the Heads of Veterinary Medicines Agencies website (www.HMA.eu ).

This section contains information on significant changes which have been made after the original procedure which are important for the quality, safety or efficacy of the product.

### Significant changes

| **Summary of change**<br>**(Application number)** | **Approval date** |
|---|---|
| This marketing authorisation was renewed unlimited.<br>(AT/V/0012/001/R/001) | 12/06/2019 |
| *** No significant changes since *** | |