SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baycox 2.5% w/v Oral Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Constituents	mg per ml	% w/v
Toltrazuril	25	2.5

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral solution.
Clear colourless to brown solution.

4. CLINICAL PARTICULARS

4.1 Target species

Broilers and Broiler Breeders

4.2 Indications for use, specifying the target species

For the treatment of Coccidiosis in Broilers and Broiler Breeders.
Baycox is effective against *Eimeria acervulina, E. brunetti, E. maxima, E. necatrix, E. tenella, E. mitis.*

4.3 Contraindications

None.

4.4 Special warnings for each target species

Baycox does not interfere with the development of immunity against coccidiosis. As with all anticoccidials, prolonged use may result in the development of resistant strains.

4.5 Special precautions for use

i. Special precautions for use in animals

Dilutions more concentrated than 1:1,000 (1 ml Baycox 2.5% to 1 litre drinking water) may result in precipitation. Predilution is not recommended.

ii. Special precautions to be taken by the person administering the medicinal product to animals

Baycox is an alkaline solution.
Wear synthetic rubber gloves when handling the product.
Wash any splashes from skin or eyes immediately with water.
Wash hands and exposed skin after use.
Do not eat, drink or smoke whilst using the product.

iii. Other precautions

Only make up sufficient drinking water for requirements.
Wash out empty container with water 3 times when medicating birds and add washings to drinking water.
Store litter from treated houses as long as possible. However, it should only be stored where there is no risk of polluting surface water or groundwater.
Do not apply to agricultural land at a rate greater than 1.5 tonnes/hectare/year.
If spreading within an NVZ ensure that the NVZ action programme rules are complied with.
The principle metabolite of toltrazuril is persistent and mobile in groundwater.

4.6 Adverse reactions (frequency and seriousness)

Not known

4.7 Use during pregnancy, lactation or lay

None.

4.8 Interaction with other medicinal products and other forms of interaction

None known.
Baycox is compatible with coccidiostats and amoebostats.

4.9 Amount(s) to be administered and administration route

Administration : via the drinking water

Dosage :
Baycox is mixed in the drinking water before use. Gentle mixing is required. Proportioning systems may be used (see Section 4.5.i above)

The recommended dose rate is 7 mg Toltrazuril per kg bodyweight per day given for 2 consecutive days. This corresponds to :

- 28 ml Baycox 2.5% Solution (equivalent to 700 mg toltrazuril) per 100 kg of bodyweight per day for 2 consecutive days.

As a guide for usage this is normally equivalent to 25 ppm (equivalent to 1 ml Baycox 2.5%) per litre of drinking water for continuous medication over 48 hours, or to 75 ppm (equivalent to 3 ml Baycox 2.5%) per litre of drinking water given for 8 hours per day, on 2 consecutive days.

Treatment Regimen

Curative treatment

Chicken : 1 medication period (over 2 days).

Only make up sufficient drinking water for requirements.

After calculation of the required amount of product, this volume should be carefully dispensed from the container into a domestic measuring jug reserved and labelled specifically for the purpose. Measurement must be made carefully to ensure correct dosage. Product must not be stored in the jug.

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

A three - five fold overdosage is readily tolerated without any symptoms. If the recommended dose is exceeded beyond 3 - 5 times there is a decrease in water intake.

4.11 Withdrawal period(s)

Meat: 18 days.
Do not use in birds producing eggs for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Toltrazuril

ATC Vet Code: QP51AJ01

5.1 Pharmacodynamic properties

Anticoccidial, active against all intracellular stages but the mode of action is unknown.

5.2 Pharmacokinetic particulars

In poultry toltrazuril is absorbed at a rate of at least 50%. The highest equivalent concentrations are found in liver. The active substance is rapidly metabolised in poultry. The main metabolite is characterised as a sulfone-derivative. About 1 week after the last dose this metabolite represents by far the most relevant residue in the animal.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Triethanolamine
Macrogol 200

6.2 Incompatibilities

None known

6.3 Shelf-life

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

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

6.4 Special precautions for storage

Do not store above 25ºC.
Following dilution in the drinking water Baycox is stable for 24 hours.
Any medicated water which is not consumed within 24 hours should be discarded safely.

6.5 Nature and composition of immediate packaging

1 litre and 5 litre white high density polyethylene bottles closed with green or black polypropylene cap (screw fit) with a red or yellow tamper evident seal.

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, if appropriate

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

7. MARKETING AUTHORISATION HOLDER

Bayer plc,
Animal Health Division,
Bayer House,
Strawberry Hill,
Newbury,
Berkshire RG14 1JA

8. MARKETING AUTHORISATION NUMBER(S)

Vm: 00010/4084

9. DATE OF FIRST AUTHORISATION

13 February 2004

10. DATE OF REVISION OF THE TEXT

December 2009