Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Baycox 2.5% Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Constituents	**mg per ml**
Toltrazuril	25

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Clear, colourless to brown oral solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Chickens.

4.2 Indications for use, specifying the target species

For the treatment and control of coccidiosis, Toltrazuril is effective against all intestinal stages of susceptible coccidia.
To assist in the development of natural immunity to coccidiosis in breeder and layer replacer stock exposed to continuous challenge of virulent strains of coccidia

4.3 Contraindications

Do not use in birds producing eggs for human consumption.

4.4 Special warnings for each target species

As with all anticoccidials, prolonged use may result in the development of resistant strains.

4.5 Special precautions for use

Special precautions for use in animals

Predilution in water at less than 1:1000 will result in the precipitation of the active ingredient.

During treatment all water available to the flock must be medicated. Treatment may be by direct application into the header tanks, or using an accurate water proportioning system.

Before use, header tanks should be emptied, thoroughly cleaned and then filled with a known volume of clean water before adding the required amount of Baycox 2.5% Solution. The resulting mixture should be stirred. Header tanks should be inspected at regular intervals for the presence of dust, algae formation and sedimentation.

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 concentrated product.
Wash any splashes from skin or eyes immediately with water.
Do not eat, drink or smoke whilst using the product.

4.6 Adverse reactions (frequency and seriousness)

Not known.

4.7 Use during pregnancy, lactation or lay

See section 4.11

4.8 Interaction with other medicinal products and other forms of interaction

Baycox is compatible with antibiotics such as enrofloxacin, ampicillin, tetracycline, tiamulin and tylosin.

4.9 Amounts to be administered and administration route

Baycox is indicated in water medication at the rate of 25 ppm (1 litre Baycox 2.5% Solution per 1000 litres of drinking water). This should be for a continuous period of 48 hours. Alternatively, it can be added at the higher level of 75 ppm (3 litres/1000 litres) for 8 hours per day on 2 successive days.

Two days treatment is sufficient for the therapy of an outbreak of clinical coccidiosis, or control of subclinical coccidiosis during the feeding of ionophores.

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

A three – five fold overdose 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)

Birds must not be slaughtered for human consumption until 14 days following last treatment.

Do not use in birds producing eggs for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Toltrazuril is an anticoccidial of the triazinetrione group with a coccidiocidal action.

ATC Vet Code: QP51AJ01

5.1 Pharmacodynamic properties

Toltrazuril induces changes in the fine structure of coccidial development stages that are mainly due to the swelling of the endoplasmic reticulum and of the Golgi apparatus and to abnormalities in the perinuclear space and disturbances in nuclear division. Toltrazuril also causes a reduction of enzymes in the respiratory chain of the parasites. Pharmacodynamic studies in laboratory animals indicated that toltrazuril had no anticoagulant, fibrinolytic, analgesic, diuretic or anticonvulsant effect. It had no effect on gastrointestinal transit time. Oral doses of up to 30 mg/kg bw had no haemodynamic or cardiac effects in anaesthetised dogs although 100mg/kg bw caused a slight tensor effect as reflected by an increase in peripheral resistance

5.2 Pharmacokinetic properties

In poultry, Toltrazuril is absorbed at a rate of at least 50%. The highest concentrations are found in the 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 animals.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Triethanolamine
Polyethylene Glycol 200

6.2 Incompatibilities

None known.

6.3 Shelf-life

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

Shelf-life after dilution or reconstitution: 24 hours. Any medicated water which is not consumed within 24 hours should be discarded.

6.4 Special precautions for storage

Do not store above 25°C.
Protect from freezing.

6.5 Nature and composition of immediate packaging

1 litre polyethylene bottle.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Bayer Limited,
Animal Health Division,
The Atrium,
Blackthorn Road,
Dublin 18

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10021/019/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

31st July 2007

10 DATE OF REVISION OF THE TEXT

1st March 2010