LABELLING

Please note: The 1000 ml bottle will have no label as there is enough space to put the leaflet information given on the 1000 ml bottle label. Consequently, for the 1000 ml bottle leaflet text and label text are the same

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

Carton and bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baycox Sheep
50 mg/ml oral suspension
Toltrazuril

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substance:
1 ml contains:
Toltrazuril 50.0 mg

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

100 ml
250 ml
1000ml

5. TARGET SPECIES

For Sheep (lambs)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal: 42 days
Not authorised for use in lactating sheep producing milk for human consumption

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

Shelf-life after first opening the immediate packaging: 3 months.
Once broached, use by…….

EXP

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leafet

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

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

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch

B. PACKAGE LEAFLET

PACKAGE LEAFLET
{(Invented) name of veterinary medicinal product <strength> pharmaceutical form <target species>}

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

Marketing authorisation holder:
To be allocated

Representative:

to be allocated (if applicable)

Manufacturer for the batch release:
KVP Pharma + Veterinär Produkte GmbH, Projensdorfer Str. 324, 24106 Kiel, Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baycox Sheep
50 mg/ml oral suspension
Toltrazuril

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

White or yellowish suspension.

1 ml contains:

Active substance:

Toltrazuril	50.0 mg

Excipients:

Sodium benzoate (E211)	2.1 mg
Sodium propionate (E281)	2.1 mg

4. INDICATION(S)

For the prevention of clinical signs of coccidiosis and reduction of coccidia shedding in lambs on farms with a confirmed history of coccidiosis caused by *Eimeria crandallis* and *Eimeria ovinoidalis*

5. CONTRAINDICATIONS

None

6. ADVERSE REACTIONS

None known

7. TARGET SPECIES

For Sheep (lambs)

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

20 mg toltrazuril per kg body weight in one single oral administration.

Each animal should be treated with a single oral dose of 20 mg toltrazuril/kg body weight corresponding to 0.4 ml oral suspension per kg body weight. To obtain maximum benefit, animals should be treated before the expected onset of clinical signs, *i.e.* in the prepatent period..
If animals are to be treated collectively rather than individually, they should be grouped according to their body weight and dosed accordingly, in order to avoid under- or over-dosing.
To ensure administration of a correct dose, body weight should be determined as accurately as possible.

0.4 ml oral suspension per kg body weight.

The ready-to-use oral suspension must be shaken before use.

9. ADVICE ON CORRECT ADMINISTRATION

Wash any splashes from skin or eyes immediately with water.

10. WITHDRAWAL PERIOD

Meat and offal: 42 days
Not authorised for use in lactating sheep producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
This veterinary medicinal product does not require any special storage conditions. Do not use after the expiry date stated on the label after “EXP” and “Shelf-life after first opening the immediate packaging: 3 months”.

12. SPECIAL WARNING(S)

- As with any antiparasiticide frequent and repeated use of antiprotozoals from the same class may lead to the development of resistance.
- It is recommended to treat all lambs in a pen
- Hygienic measures may reduce the risk of ovine coccidiosis. It is therefore, recommended to improve concomitantly the hygienic conditions in the concerned facility, particularly dryness and cleanliness.
- To obtain maximum benefit, animals should be treated before the expected onset of clinical signs, i.e. in the prepatent period.
- Wash any splashes from skin or eyes immediately with water
- The metabolite of toltrazuril, toltrazuril sulfone (ponazuril) is a persistent (half-life >1 year) and mobile compound and has adverse effects on both the growth and emergence of plants. Given the persistent properties of ponazuril repeated spreading of manure from treated animals may lead to

an accumulation in the soil and consequently a risk to plants. The accumulation of ponazuril in soil together with its mobility also leads to a risk of leaching to groundwater.

- For environmental reasons: Lambs kept throughout the whole life span indoors under an intensive rearing system must not be treated beyond the age of 6 weeks or body weight of more than 20 kg at treatment. Manure from these animals should only be applied to the same piece of land every third year.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

To be allocated

15. OTHER INFORMATION

100 ml
250 ml
1000 ml

Not all pack sizes may be marketed.