1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baycox Bovis
50mg/ml oral suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:
Active substance:

Toltrazuril	50.0 mg

Excipient(s):

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

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral suspension
White or yellowish suspension

4. CLINICAL PARTICULARS

4.1 Target species

Cattle (calves on dairy farms)

4.2 Indications for use, specifying the target species

For the prevention of clinical signs of coccidiosis and reduction of coccidia shedding in housed calves replacing cows producing milk for human consumption (dairy cows) on farms with a confirmed history of coccidiosis caused by *Eimeria bovis* or *Eimeria zuernii.*

4.3 Contraindications

For environmental reasons:

- Do not use in calves weighing more than 80 kg bodyweight.
- Do not use in fattening units such as veal or beef calves
- For more details see sections 4.5, other precautions and section 5, environmental properties.

4.4 Special warnings <for each target species>

- 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 calves in a pen
- Hygienic measures may reduce the risk of bovine 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.
- To alter the course of an established clinical coccidial infection, in individual animals already showing signs of diarrhoea, additional supportive therapy may be required.

4.5 Special precautions for use

Special precautions for use in animals
None

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Wash any splashes from skin or eyes immediately with water.

Other precautions

The major metabolite of toltrazuril, toltrazuril sulfone (ponazuril), has been shown to be both persistent (half-life >1 year) and mobile in soil and to be toxic to plants.

In order to prevent any adverse effects on plants and possible contamination of groundwater manure from treated calves must not be spread onto land without dilution with manure from untreated cows. Manure from treated calves must be diluted with at least 3 times the weight of manure from mature cows before it can be spread onto land.

4.6 Adverse reactions (frequency and seriousness)
None known

4.7 Use during pregnancy, lactation or lay
Not applicable

4.8 Interaction with other medicinal products and other forms of interaction
None known

4.9 Amounts to be administered and administration route
- Each animal should be treated with a single oral dose of 15 mg toltrazuril/kg body weight corresponding to 3.0 ml oral suspension per 10 kg body weight.
- The ready-to-use oral suspension must be shaken before use.
- For the treatment of a group of animals of the same breed and same or similar age, the dosing should be done according to the heaviest animal of this group.
- To ensure administration of a correct dose, body weight should be determined as accurately as possible
- To obtain maximum benefit, animals should be treated before the expected onset of clinical signs, i.e. in the prepatent period.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary
A threefold overdose is well tolerated by calves without signs of intolerance.

4.11 Withdrawal period(s)
Meat and offal: 63 days
Milk: Not permitted for use in lactating animals producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiparasitic products, insecticides and repellents, antiprotozoals, agents against protozoal diseases, triazines, toltrazuril. ATCvet code: QP 51 AJ 01

5.1 Pharmacodynamic properties

Toltrazuril is a triazinon derivative. It acts against coccidia of the genus *Eimeria.* It is active against all intracellular development stages of coccidia of the merogony (asexual multiplication) and gamogony (sexual phase). All stages are destroyed, and hence the mode of action is coccidiocidal.

5.2 Pharmacokinetic particulars

After oral administration in cattle toltrazuril is slowly absorbed. The maximal plasma concentration (Cmax = 36.6 mg/l) was observed between 24 and 48 hours (geometric mean 33.9 hours) following oral administration. The elimination of toltrazuril is slow with a terminal half-life time of approximately 2.5 days (64.2 hours). The main metabolite is characterised as toltrazuril sulfone. The major route of excretion is *via* the faeces.

5.3 Environmental properties

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. See sections 4.3 and 4.5.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium benzoate (E211)
Sodium propionate (E281)
Sodium docusate
Simethicone emulsion
Bentonite
Citric acid, anhydrous
Xanthan gum
Propylene glycol
Purified water

6.2 Incompatibilities

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

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 5 years
Shelf-life after first opening the container: ~~3~~6 months.

6.4. Special precautions for storage

The veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

High density polyethylene bottles or back packs containing 100, 250, 1000 or 2500 ml of a white or yellowish suspension with a blue polypropylene screw cap for the 100 ml bottle, a green one for the 250 ml bottle and 1000 ml bottle and a white polypropylene screw cap with induction seal for the 1000 ml back pack and 2500ml back pack.

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

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

7. MARKETING AUTHORISATION HOLDER

To be filled in by subsidiary

8. MARKETING AUTHORISATION NUMBER(S)

To be allocated

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

To be allocated

10 DATE OF REVISION OF THE TEXT

—

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

Labelling
Baycox Bovis

Renewal
DK/V/0109/001/R/001

DAY 90

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

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baycox Bovis
50mg/ml oral suspension
Toltrazuril

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains:
Active substance:

Toltrazuril	50.0 mg

Excipients:

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

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

100 ml
250 ml
1000 ml
2500 ml

5. TARGET SPECIES

Cattle (calves on dairy farms)

6. INDICATIONS

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Shake well before use

8. WITHDRAWAL PERIOD

Meat and offal: 63 days
Milk: Not permitted for use in lactating animals producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

User Warnings: Wash any splashes from skin or eyes immediately with water

10. EXPIRY DATE

Exp.: MM/YYYY

Shelf-life after first opening the container: ~~3~~6 months

Once broached, use by

11. SPECIAL STORAGE CONDITIONS

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

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

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

To be filled in by subsidiary

16. MARKETING AUTHORISATION NUMBER(S)

To be allocated

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

B. Package Leaflet

Baycox Bovis

Renewal
DK/V/0109/001/R/001

DAY 90

PACKAGE LEAFLET

Baycox Bovis, 50 mg/ml oral suspension, calves

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 filled in by subsidiary

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baycox Bovis
50 mg/ml oral suspension
Toltrazuril

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

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 housed calves replacing cows producing milk for human consumption (dairy cows) on farms with a confirmed history of coccidiosis caused by *Eimeria bovis* or *Eimeria zuernii.*

5. CONTRAINDICATIONS

For environmental reasons:
Do not use in calves weighing more than 80 kg bodyweight.
Do not use in fattening units such as veal or beef calves
For more details see sections 12 "Special Warnings"

6. ADVERSE REACTIONS

None known
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle (calves on dairy farms)

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

- Each animal should be treated with a single oral dose of 15 mg toltrazuril/kg body weight corresponding to 3.0 ml oral suspension per 10 kg body weight.
- The ready-to-use oral suspension must be shaken before use.
- For the treatment of a group of animals of the same breed and same or similar age, the dosing should be done according to the heaviest animal of this group.
- To ensure administration of a correct dose, body weight should be determined as accurately as possible
- To obtain maximum benefit, animals should be treated before the expected onset of clinical signs, i.e. in the prepatent period.

9. ADVICE ON CORRECT ADMINISTRATION

None

10. WITHDRAWAL PERIOD

Meat and offal: 63 days
Milk: Not permitted for use in lactating animals 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
- Shelf-life after first opening the container: ~~3~~6 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 container should be discarded should be worked out. This discard date should be written in the space provided on the label

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 calves in a pen.
- Hygienic measures may reduce the risk of bovine 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.
- To alter the course of an established clinical coccidial infection, in individual animals already showing signs of diarrhoea, additional supportive therapy may be required.
- The major metabolite of toltrazuril, toltrazuril sulfone (ponazuril), has been shown to be both persistent (half-life > 1 year) and mobile in soil and to be toxic to plants.
- In order to prevent any adverse effects on plants and possible contamination of groundwater manure from treated calves must not be spread onto land without dilution with manure from untreated cows. Manure from treated calves must be diluted with at least 3 times the weight of manure from mature cows before it can be spread onto land.
- Use during pregnancy, lactation or lay: Not applicable
- Interaction with other medicinal products and other forms of interaction: None known
- A threefold overdose is well tolerated by calves without signs of intolerance.
- In the absence of compatibility studies, this veterinary product must not be mixed with other veterinary medicinal products.

- User Warnings:
  Wash any splashes from skin or eyes immediately with water

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

Package sizes:
100 ml bottle
250 ml bottle
1000 ml bottle
1000 ml back pack
2500 ml back pack
Not all pack sizes may be marketed.