SUMMARY OF PRODUCT CHARACTERISTICS

Baycox 50 mg/ml
Oral Suspension
Target Species: Pig

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baycox® 50 mg/ml
oral suspension, pig

For Finland
Baycox® vet 50 mg/ml,
oral suspension, pig

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
1 ml contains:

Toltrazuril	50 mg

Excipients:

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

Pig (Piglet, 3 – 5 days old).

4.2 Indications for use, specifying the target species

For the prevention of clinical signs of coccidiosis in neonatal piglets (3 – 5 days old) on farms with a confirmed history of coccidiosis caused by *Isospora suis*.

4.3 Contraindications

None

4.4 Special warnings

None

4.5 Special precautions for use

Special precautions for use in animals

None known

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.

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, e.g. there is no interaction in combination with iron supplementation.

4.9 Amounts to be administered and administration route

Individual animal treatment.
Each pig to be treated on day 3-5 of life with a single oral dose of 20 mg toltrazuril/kg body weight corresponding to 0.4 ml oral suspension per kg body weight.
Due to the small volumes required to treat individual piglets, use of dosing equipment with a dose accuracy of 0.1 ml is recommended.

The oral suspension must be shaken before use.

Treatment during an outbreak will be of limited value for the individual piglet because of damage to the small intestine having already occurred.

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

No signs of intolerance were observed in piglets up to threefold overdose

4.11 Withdrawal period(s)

Meat and offal: 77 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiprotozoal product, ATCvet code: QP 51 AJ 01

5.1 Pharmacodynamic properties

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

5.2 Pharmacokinetic particulars

After oral administration toltrazuril is slowly absorbed with a bioavailability of ≥70%. The main metabolite is characterised as toltrazuril sulfone. The elimination of toltrazuril is slow with a half-life elimination time around 3 days. The major route of excretion is via the faeces.

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 absence of compatibility studies this veterinary medicinal product must not be mixed with other veterinary medicines.

6.3 Shelf life

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

6.4. Special precautions for storage

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

6.5 Nature and composition of immediate packaging

High density polyethylene bottles containing 100, 250 or 1000 ml of a white or yellowish suspension with a blue polypropylene screw cap for the 100 ml bottle and a green polypropylene screw cap for the 250 ml and 1000 ml bottle, the 100 and 250 ml bottles are provided in card boxes.

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 should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

To be allocated nationally
In DK
Bayer HealthCare AG
Business Group Animal Health
51368 Leverkusen
Germany

8. MARKETING AUTHORISATION NUMBER(S)

To be allocated nationally
In DK
18081 (DK)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

To be allocated nationally
In DK
9 May 2000 (old DK)
10 October 2002 (current EU)

10 DATE OF REVISION OF THE TEXT

To be allocated

PROHIBITION OF SALE, SUPPLY AND/OR USE

To be allocated nationally
In DK
POM

LABELLING AND PACKAGE LEAFLET

Baycox 50 mg/ml
Oral Suspension
Target Species: Pig

For the 100, 250 and 1000 ml bottle

For the 100 and 250 ml bottle there is a carton and the leaflet will be included in the carton.

For the 1000 ml bottle there is no carton but the leaflet text is presented on the bottle together with the label text via a multi-layer adhesive label.

A. LABELLING

Baycox 50 mg/ml
Oral Suspension
Target Species: Pig

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

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baycox® 50 mg/ml
oral suspension, pig

For Finland
Baycox® vet 50 mg/ml
oral suspension, pig

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substance:
1 ml contains:
Toltrazuril 50 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

5. TARGET SPECIES

Pig (Piglet, 3 – 5 days old)

6. INDICATION(S)

For the prevention of clinical signs of coccidiosis in neonatal piglets (3 – 5 days old) on farms with a confirmed history of coccidiosis caused by Isospora suis

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use. Shake well before use

8. WITHDRAWAL PERIOD

Meat and offal: 77 days

9. SPECIAL WARNING(S), IF NECESSARY

-

10. EXPIRY DATE

MM/YYYY
Shelf-life after first opening the container: ~~3~~6 months.

11. SPECIAL STORAGE CONDITIONS

-

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

Any unused veterinary medicinal product or waste material 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 subsiduary

16. MARKETING AUTHORISATION NUMBER(S)

To be allocated

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

B. PACKAGE LEAFLET

Baycox 50 mg/ml
Oral Suspension
Target Species: Pig

PACKAGE LEAFLET

Baycox® 50 mg/ml
oral suspension, pig

For Finland
Baycox® vet 50 mg/ml
oral suspension, pig

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

Marketing authorisation holder and manufacturer:
To be filled by the 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® 50 mg/ml
oral suspension, pig

For Finland
Baycox® vet 50 mg/ml
oral suspension, pig

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

Active substance:
1 ml contains:

Toltrazuril	50 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 in neonatal piglets (3 – 5 days old) on farms with a confirmed history of coccidiosis caused by Isospora suis.

5. CONTRAINDICATIONS

None

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

Pig (Piglet, 3 – 5 days old)

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

Individual animal treatment.
Each pig to be treated on day 3-5 of life with a single oral dose of 20 mg toltrazuril/kg body weight corresponding to 0.4 ml oral suspension per kg body weight.
Due to the small volumes required to treat individual piglets, use of dosing equipment with a dose accuracy of 0.1 ml is recommended.

The oral suspension must be shaken before use.

Treatment during an outbreak will be of limited value for the individual piglet because of damage to the small intestine having already occurred.

9. ADVICE ON CORRECT ADMINISTRATION

-

10. WITHDRAWAL PERIOD

Meat and offal: 77 days

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.

12. SPECIAL WARNING(S)

In absence of compatibility studies this veterinary medicinal product must not be mixed with other veterinary medicines.
Wash any splashes from skin or eyes immediately with water.-

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

To be allocated

15. OTHER INFORMATION>

Not all pack sizes may be marketed.
None known, e.g. there is no interaction in combination with iron supplementation.
No signs of intolerance were observed in piglets up to threefold overdose