[Version 8.2,01/2021]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Toltramax 50 mg/ml oral suspension for pigs *(in Austria, Belgium, Czech Republic, Denmark, France, Germany, Greece, Hungary, Italy, Netherlands, Romania, Spain and United Kingdom)*

Scancox 50 mg/ml oral suspension for pigs *(in Poland)*

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:

Active substance:

Toltrazuril	50 mg

Excipients:

Sodium benzoate (E211)	2 mg
Sodium propionate (E281)	2 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral suspension.
White or almost white suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Pig (Piglets 3 to 5 days old).

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

Do not use in case of hypersensitivity to the active substance or to any of the excipients.

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 animals in a pen.
Hygienic measures may reduce the risk of coccidiosis. It is therefore, recommended to improve concomitantly the hygienic conditions in the concerned facility, particularly dryness and cleanliness.

4.5 Special precautions for use

Special precautions for use in animals
To alter the course of an established clinical coccidial infection, in individual animals already showing signs of diarrhoea, additional supportive therapy may be required.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
In case of accidental ingestion seek medical advice immediately and show the package leaflet or the label to the physician.
This product may cause allergic reactions in those that are sensitive.
People with known hypersensitivity to toltrazuril should avoid contact with the product.
The product may cause irritation if it comes into contact with the skin or eyes.
Avoid skin and eye contact with the product.
In case of accidental eye exposure, wash with plenty of water.
In case of accidental contact with skin, rinse immediately with water.
Wash hands and exposed skin after use.
Do not eat, drink or smoke whilst using the product.

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

For oral use. 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.
The weight of animal should be accurately determined before treatment.
The oral suspension must be shaken before use.
Due to the small volumes required to treat individual piglets, use of dosing equipment with a dose accuracy of 0.1 ml is recommended.
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 adverse effect has been observed in piglets after administration of a threefold overdose.

4.11 Withdrawal period(s)

Meat and offal: 77 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiprotozoals
ATC vet code: QP51AJ01

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 maximum concentration (Cmax) of toltrazuril is of 15.1 µg/ml and is obtained after around 24 h. 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)
Citric acid, monohydrate
Xanthan gum
Propylene glycol
Purified water

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal 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: 2 years
Shelf-life after first opening the immediate packaging: 3 months

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

White high density polyethylene bottles containing 250 or 1000 ml of suspension with a white high density polyethylene screw cap.
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 materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements

7. MARKETING AUTHORISATION HOLDER

Lavet Pharmaceuticals Ltd.
Batthyány u. 6., Kistarcsa, H-2143
Hungary

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22/02/2012
Date of last renewal: 07/11/2016

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE
Not applicable

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

White high density polyethylene bottles containing 250 ml of suspension with a white high density polyethylene screw cap.

White high density polyethylene bottles containing 1000 ml of suspension with a white high density polyethylene screw cap.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Toltramax 50 mg/ml oral suspension for pigs *(in Austria, Belgium, Czech Republic, Denmark, France, Germany, Greece, Hungary, Italy, Netherlands, Romania, Spain and United Kingdom)*

Scancox 50 mg/ml oral suspension for pigs (*in Poland)*

Toltrazuril

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains:
Active substance:
Toltrazuril 50 mg
Excipients:
Sodium benzoate (E211) 2 mg
Sodium propionate (E281) 2 mg

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

250 ml
1000 ml

5. TARGET SPECIES

Pig (Piglets 3 to 5 days old).

6. INDICATION(S)

For the prevention of clinical signs of coccidiosis in neonatal piglets (3 to 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.
Oral use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Meat and offal: 77 days

9. SPECIAL WARNING(S), IF NECESSARY

Wash any splashes from skin or eyes immediately with water.
Wash hands after use. Do not smoke, eat or drink whilst handling the product.
People with known hypersensitivity to toltrazuril should avoid contact with the product.

10. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening the container: 3 months
Once opened, use by…

11. SPECIAL STORAGE CONDITIONS

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

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

Dispose of waste material in accordance with local 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 SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Lavet Pharmaceuticals Ltd.
Batthyány u. 6., Kistarcsa, H-2143
Hungary

Manufacturer for batch release:
Lavet Pharmaceuticals Ltd.,
Batthyány u. 6., Kistarcsa, H-2143
Hungary
(in Italy)

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch: {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Toltramax 50 mg/ml oral suspension for pigs
(in Austria, Belgium, Czech Republic, Denmark, France, Germany, Greece, Hungary, Italy, Netherlands, Romania, Spain and United Kingdom)

Scancox 50 mg/ml oral suspension for pigs
(in Poland)

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 responsible for batch release:
Lavet Pharmaceuticals Ltd.,
Batthyány u. 6., Kistarcsa, H-2143
Hungary

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Toltramax 50 mg/ml oral suspension for pigs
(in Austria, Belgium, Czech Republic, Denmark, France, Germany, Greece, Hungary, Italy, Netherlands, Romania, Spain and United Kingdom)

Scancox 50 mg/ml oral suspension for pigs *(in Poland)*

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

1 ml contains:

Active substance:	
Toltrazuril	50 mg
Excipients:	
Sodium benzoate (E211)	2 mg
Sodium propionate (E281)	2 mg

White or almost white suspension.

4. INDICATION(S)

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

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Pig (Piglets 3 to 5 days old).

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

For oral use.
The oral suspension must be shaken before use.
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. 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

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 weight of animal should be accurately determined before treatment.

10. WITHDRAWAL PERIOD(S)

Meat and offal: 77 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of sight and reach of children.
Do not use after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
Shelf-life after first opening the container: 3 months

12. SPECIAL WARNING(S)

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 animals in a pen.
Hygienic measures may reduce the risk of coccidiosis. It is therefore, recommended to improve concomitantly the hygienic conditions in the concerned facility, particularly dryness and cleanliness.

Special precautions for use in animals:

To alter the course of an established clinical coccidial infection, in individual animals already showing signs of diarrhoea, additional supportive therapy may be required.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental ingestion seek medical advice immediately and show the package leaflet or the label to the physician.

People with known hypersensitivity to toltrazuril, or any of the excipients, should avoid contact with the veterinary medicinal product.
Avoid skin and eye contact with the product.
Wash any splashes from skin or eyes immediately with water.
Do not eat, drink or smoke whilst using the product.

Interaction with other medicinal products and other forms of interaction
None known, e.g. there is no interaction in combination with iron supplementation.

Overdose (symptoms, emergency procedures, antidotes):
No adverse effect has been observed in piglets after administration of a threefold overdose.

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

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

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

White high density polyethylene bottles containing 250 or 1000 ml of suspension with a white high density polyethylene screw cap.

Not all pack sizes may be marketed.

For animal treatment only.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.