# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Toltramax 50 mg/ml oral suspension for pigs
*(in Cyprus, Czech Republic, Denmark, France, Greece, Hungary, Italy, Latvia, Lithuania, Portugal, Romania, Spain and United Kingdom)*

Dozuril Pig 50 mg/ml oral suspension for pigs *(in Austria, Belgium, Germany, Netherlands)*

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

**i) 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.

**ii) 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, ATCvet 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 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.
Ottó u. 14
Budapest
H-1161 Hungary

## 8. MARKETING AUTHORISATION NUMBER

Vm 32823/4009

## 9. DATE OF FIRST AUTHORISATION

04 April 2012

## 10. DATE OF REVISION OF THE TEXT

March 2017