

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Toltramax 50 mg/ml oral suspension for pigs  
Toltrazuril

### **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 (C<sub>max</sub>) 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.  
Batthyány u. 6.  
Kistarcsa  
H-2143

### **8. MARKETING AUTHORISATION NUMBER**

Vm 32823/4009

### **9. DATE OF FIRST AUTHORISATION**

04 April 2012

### **10. DATE OF REVISION OF THE TEXT**

March 2021

Approved 24 March 2021

A handwritten signature in black ink, appearing to read "A. Hunter". The signature is stylized with a large initial 'A' and a trailing flourish.