

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZORABEL 50 mg/ml Oral Suspension for pigs [CZ, DK, ES, HU, IE, PL, PT, SK]

ZORABEL vet 50 mg/ml Oral Suspension for pigs [SE]

BUSERIL 50 mg/ml Oral Suspension for pigs [FR]

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains :

### Active substance:

Toltrazuril 50 mg

### Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Sodium Benzoate (E 211)	2.1 mg
Sodium Propionate (E 281)	2.1 mg
Sodium docusate	
Simethicone emulsion	
Bentonite	
Citric acid, anhydrous	
Xanthan gum	
Propylene glycol	
Purified water	

White or cream suspension.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Pigs (Piglets 3 – 5 days old).

### 3.2 Indications for use for each 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*.

### 3.3 Contraindications

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

### 3.4 Special warnings

As with any antiparasiticide, frequent and prolonged use of an antiprotozoal of the same class of active substance and underdosing due to underestimation of the live weigh may result in the development of resistances.

It is recommended to treat all piglets in a litter.

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.

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.

### **3.5 Special precautions for use**

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

People with known hypersensitivity to toltrazuril, or to any of the excipients, should avoid contact with the veterinary medicinal product.

Avoid skin and eye contact with the veterinary medicinal product.

In case of accidental exposure, wash any splashes from skin or eyes immediately with water.

Do not eat, drink or smoke whilst using the veterinary medicinal product.

Special precautions for the protection of the environment:

Not applicable.

### **3.6 Adverse events**

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See package leaflet for respective contact details.

### **3.7 Use during pregnancy, lactation or lay**

Not applicable.

### **3.8 Interaction with other medicinal products and other forms of interaction**

None known, e.g there is no interaction in combination with iron supplementation.

### **3.9 Administration routes and dosage**

Oral use.

Individual animal treatment.

Treat 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 veterinary medicinal product per kg body weight).

Due to the small volumes requires to treat individual piglets, use of dosing equipment with a dose accuracy of 0.1 ml is recommended.

To ensure a correct dosage, body weight should be determined as accurately as possible.

The oral suspension must be shaken well before use until complete resuspension. The suspension should be white or cream.

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

### **3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)**

A threefold overdose is well tolerated by healthy piglets.

### **3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance**

Not applicable

### **3.12 Withdrawal periods**

Meat and offal: 73 days

## **4. PHARMACOLOGICAL INFORMATION**

### **4.1 ATCvet code:**

QP51AJ01

### **4.2 Pharmacodynamics**

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

### **4.3 Pharmacokinetics**

After oral administration toltrazuril is slowly absorbed with a bioavailability of  $\geq 70\%$ . 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.

## **5. PHARMACEUTICAL PARTICULARS**

### **5.1 Major incompatibilities**

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

### **5.2 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale: 3 years

Shelf life after first opening the immediate packaging: 3 months

### **5.3 Special precautions for storage**

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

### **5.4 Nature and composition of immediate packaging**

The veterinary medicinal product is packaged in high polyethylene density bottle with high-density polyethylene cap with strapping and welding disk of 100 ml, 250 ml or 1L.

Pack size:

Bottle of 1 L

Cardboard box with 1 bottle of 100 ml.

Cardboard box with 1 bottle of 250 ml.

Cardboard box with 15 bottles of 250 ml.

Not all pack sizes may be marketed.

**5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products**

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

**6. NAME OF THE MARKETING AUTHORISATION HOLDER**

VETPHARMA ANIMAL HEALTH, S.L

**7. MARKETING AUTHORISATION NUMBER(S)**

**8. DATE OF FIRST AUTHORISATION**

Date of first authorization: {DD/MM/YYYY}

**9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS**

{DD/MM/YYYY}

**10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (<https://medicines.health.europa.eu/veterinary>).