# SUMMARY OF PRODUCT CHARACTERISTICS

## 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:**
Sodium Benzoate (E 211) 2.1 mg
Sodium Propionate (E 281) 2.1 mg

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Oral suspension
White or cream suspension

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Pigs (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

Do not use in cases of known 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 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.

## 4.5 Special precautions for use

Special precautions for use in animals

Not applicable.

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

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

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.

The weight of animal should be accurately determined before treatment.

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.

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

A threefold overdose is well tolerated by healthy piglets.

## 4.11 Withdrawal period(s)

Meat and offal: 73 days

## 5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiprotozoals. Triazines.
ATC vet code: QP51AJ01

### 5.1 Pharmacodynamic properties

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.

### 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 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: 3 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

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 unit of 100 ml bottle
-Cardboard box with 1 unit of 250 ml bottle
-Cardboard box with 15 bottles of 250 ml.
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 product should be disposed of in accordance with local requirements.

## 7. MARKETING AUTHORISATION HOLDER

VETPHARMA ANIMAL HEALTH, S.L
Les Corts, 23
08028 Barcelona
SPAIN

## 8. MARKETING AUTHORISATION NUMBER(S)

## 9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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

## 10 DATE OF REVISION OF THE TEXT

## PROHIBITION OF SALE, SUPPLY AND/OR USE

For animal treatment only. To be supplied only on veterinary prescription.
Administration under control or supervision of a veterinary surgeon.