Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Espacox 50 mg/ml oral suspension for pigs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Toltrazuril	50	mg

Excipients:

Sodium benzoate (E211)	2.1	mg
Sodium propionate (E281)	2.1	mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension.
White or yellowish suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs (Piglets, 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 *Cystoisospora suis* (*Isospora suis*).

4.3 Contraindications

Do not use in cases 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 prolonged use of an antiprotozoal of the same class of active substance and underdosing due to underestimation of the live weight 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
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.
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 exposure, wash any splashes from skin or eyes 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 interactions

None known.
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 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 required to treat individual piglets, use of dosing equipment with a dose accuracy of 0.1 ml is recommended.
The oral suspension must be shaken before use.
Treatment during an outbreak will be of limited value for the individual piglet because of damage to the small intestine having already occurred.
The weight of animal should be accurately determined before treatment.

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

No signs of intolerance were observed in piglets up to threefold overdose.

4.11 Withdrawal period(s)

Meat and offal: 73 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiprotozoals. Triazines.
ATCvet code: QP51AJ01

5.1 Pharmacodynamic properties

Toltrazuril is a triazinon derivative. It acts against coccidia of the genus *Isospora*. It isacting 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 ^{3}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)
Docusate sodium
Bentonite
Xanthan gum
Propylene glycol
Citric acid, anhydrous (for pH-adjustment)
Simethicone emulsion
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: 6 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

High density polyethylene (HDPE) bottle with a nominal capacity of 250 or 1000 ml. The bottles are heat-sealed with a polyethylene (PE) foil and are closed with a screw cap made of HDPE equipped with a security system to give an airtight sealing.

<u>Package sizes:</u>
Bottle of 1 L
Cardboard box with 1 bottle of 250 ml
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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

Industrial Veterinaria, S.A.
Esmeralda 19
E-08950 Espluges de Llobregat
Barcelona
Spain

8 MARKETING AUTHORISATION NUMBER(S)

VPA10509/005/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 04 July 2014
Date of last renewal: 12 April 2019

10 DATE OF REVISION OF THE TEXT

April 2019