1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Espacox 50 mg/ml oral suspension for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
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 (E211)	2.1 mg
Sodium propionate (E281)	2.1 mg
Docusate sodium	
Bentonite	
Xanthan gum	
Propylene glycol	
Citric acid (for pH-adjustment)	
Simethicone emulsion	
Purified water	

White or yellowish 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 *Cystoisospora suis* (*Isospora suis*).

3.3 Contraindications

Do not use in cases of 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 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Not applicable.

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.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
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.

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 the 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.
There is no interaction in combination with iron supplementation.

3.9 Administration routes and dosage

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

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

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

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 : QP51BC01

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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.

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: 2 years.
Shelf life after first opening the immediate packaging: 6 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

High density polyethylene (HDPE) bottle. The bottle is heat-sealed with a polyethylene (PE) foil and is closed with a screw cap made of HDPE equipped with a security system to give an airtight sealing.

Package sizes:
Cardboard box with 1 bottle of 250 ml
Bottle of 1l.

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

Industrial Veterinaria, S.A.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10509/005/001

8. DATE OF FIRST AUTHORISATION

04/07/2014

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

18/07/2025

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).