

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARTON BOX
250 ml and BOTTLE OF 1 l}**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Espacox 50 mg/ml oral suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Toltrazuril 50 mg

3. PACKAGE SIZE

250 ml

1 l

4. TARGET SPECIES

Pigs (Piglets, 3 - 5 days old).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

Withdrawal periods:

Meat and offal: 73 days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 6 months.

Once broached, use by:

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Industrial Veterinaria, S.A.

14. MARKETING AUTHORISATION NUMBER

Vm 36547/4004

15. BATCH NUMBER

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {LABEL 250
ml}**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Espacox 50 mg/ml oral suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Toltrazuril 50 mg

3. TARGET SPECIES

Pigs (Piglets, 3 - 5 days old).

4. ROUTES OF ADMINISTRATION

Oral use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: 73 days

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use within 6 months.
Once broached, use by:

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Industrial Veterinaria, S.A.

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Espacox 50 mg/ml oral suspension for pigs

2. Composition

Each ml contains:

Active substances:

Toltrazuril 50 mg

Excipients:

Sodium benzoate (E211) 2.1 mg

Sodium propionate (E281) 2.1 mg

White or yellowish suspension.

3. Target species

Pigs (Piglets, 3 - 5 days old).

4. Indications for use

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*).

5. Contraindications

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

6. Special warnings

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.

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

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.

Interaction with other medicinal products and other forms of interaction:

None known.

There is no interaction in combination with iron supplementation

Overdose:

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

Major incompatibilities:

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

7. Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

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).

9. Advice on correct administration

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.

10. Withdrawal periods

Meat and offal: 73 days

11. Special storage precautions

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

Shelf-life after first opening the immediate packaging: 6 months.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 36547/4004

Package sizes:

Cardboard box with 1 bottle of 250 ml.

Bottle of 1 l.

Not all pack sizes may be marketed.

15. PID link (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder:

Industrial Veterinaria, S.A.

Calle Esmeralda, 19

E-08950 Esplugues de Llobregat

Spain

Manufacturer responsible for batch release:

Industrial Veterinaria, S.A.

Esmeralda 19

08950 Esplugues de Llobregat (Barcelona) Spain

aniMedica GmbH

Im Südfeld 9

48308 Senden-Bösensell Germany

Local representatives and contact details to report suspected adverse reactions:

FORTE Healthcare Limited
Block 3, Unit 9
CityNorth Business Campus
Stamullen, Co. Meath. K32 D990
Republic of Ireland
IE: +353 1 841 7666
UK: +44 1292 800013

17. Other information

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Gavin Hall

Approved: 03 September 2025