1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dozuril 50 mg/ml oral suspension for pigs

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 (E211)	2.1 mg
Sodium propionate (E281)	2.1 mg
Sodium docusate	
Bentonite	
Xanthan Gum (E415)	
Propylene glycol (E1520)	
Citric acid, anhydrous	
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*.

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 repeated use of antiprotozoals from the same class may lead to the development of resistance.
It is recommended to treat all animals in a pen. 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 should avoid contact with this veterinary medicinal product.
Avoid skin and eye contact with the veterinary medicinal product.
Wash any splashes from skin or eyes immediately with water.
Do not eat, drink or smoke while 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 the label 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 on day 3-5 of life with a single oral dose of 20 mg toltrazuril per kg body weight corresponding to 0.4 ml oral suspension 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.
The weight of the animals should be accurately determined before administration.
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: 61 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:
QP51BC01

4.2 Pharmacodynamics
Toltrazuril is a triazinon derivative. It acts against coccidia of the genus *Cystoisospora*. It is acting against all intracellular development stages of coccidia, of the merogony (asexual multiplication) and gametogony (sexual stage). 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 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: 4 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 bottles with a white high density polyethylene screw cap containing 250 ml and 1000 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

Dopharma Research B.V.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10791/016/001

8. DATE OF FIRST AUTHORISATION

27 May 2022

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

13 September 2024

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).