1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Interzuril 50 mg/ml oral suspension for Piglets, Calves and Lambs

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
Citric acid, monohydrate (for pH adjustment)	
Sodium hydroxide (for pH adjustment)	
Xanthan gum	
Aluminium magnesium silicate	
Sodium laurilsulfate	
Propylene glycol	
Simethicone emulsion	
Purified water	

White or yellowish suspension.

3. CLINICAL INFORMATION

3.1 Target species

Pigs (piglets), Cattle (calves) and Sheep (lambs).

3.2 Indications for use for each target species

Piglets: For the prevention of clinical signs of coccidiosis in neonatal piglets on farms with a confirmed history of coccidiosis caused by *Cystoisospora suis*.

Calves: For the prevention of clinical signs of coccidiosis and reduction of coccidia shedding in housed calves replacing cows producing milk for human consumption (dairy cows) on farms with a confirmed history of coccidiosis caused by *Eimeria bovis* or *Eimeria zuernii*.

Lambs: For the prevention of clinical signs of coccidiosis and reduction of coccidia shedding in lambs on farms with a confirmed history of coccidiosis caused by *Eimeria crandallis* and *Eimeria ovinoidalis*.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
For environmental reasons:
Do not use in calves weighing more than 80 kg bodyweight.
Do not use in fattening units such as veal or beef calves.
For more details see sections 3.5, other precautions and section 4.3, environmental properties.

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 with regard to 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.

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 any of the excipients, should avoid contact with the veterinary medicinal product.
This product can cause skin and eye irritation.
Avoid skin and eye contact with the product.
In case of accidental exposure to the skin or eyes, wash the affected area thoroughly with plenty of water.
If irritation persists, seek medical advice and show the package leaflet or the label to the physician.
Do not eat, drink or smoke whilst using the product.

Special precautions for the protection of the environment:

The major metabolite of toltrazuril, toltrazuril sulfone (ponazuril), has been shown to be both persistent (half-life >1 year) and mobile in soil and to be toxic to plants.

Calves: In order to prevent any adverse effects on plants and possible contamination of groundwater manure from treated calves must not be spread onto land without dilution with manure from untreated cows. Manure from treated calves must be diluted with at least 3 times the weight of manure from mature cows before it can be spread onto land.

Lambs: kept throughout the whole life span indoors under an intensive rearing system must not be treated beyond the age of 6 weeks or body weight of more than 20 kg at treatment. Manure from these animals should only be applied to the same piece of land every third year.

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.

3.9 Administration routes and dosage

All Species
Oral use.
The oral suspension must be shaken before use.
To ensure a correct dose, body weight should be determined as accurately as possible.

Piglets
Individual animal treatment.
Each piglet should be treated between days 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.
Treatment during an outbreak will be of limited value for the individual piglet because of damage to the small intestine having already occurred.

Calves
Each animal should be treated with a single oral dose of 15 mg toltrazuril/kg body weight corresponding to 3.0 ml oral suspension per 10 kg body weight.
If animals are to be treated collectively rather than individually, reasonably homogeneous groups of the same breed and same or similar age should be set up, and all animals of a group should be dosed at the rate corresponding to the heaviest one.

Lambs
Each animal should be treated with a single oral dose of 20 mg toltrazuril/kg body weight corresponding to 0.4 ml oral suspension per kg body weight. If animals are to be treated collectively rather than individually, reasonably homogeneous groups should be set up, and all animals of a group should be dosed at the rate corresponding to the heaviest one.

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

No signs of intolerance were reported in healthy piglets and calves after oral administration of a threefold overdose.

No signs of overdose have been observed in lamb safety studies with threefold overdose at a single treatment and twofold overdose treatment on 2 consecutive days.

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

Piglets
Meat and offal: 77 days.

Calves
Meat and offal: 63 days.
Not authorised for use in animals producing milk for human consumption.

Lambs
Meat and offal: 42 days.
Not authorised for use in animals producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code : QP51AJ01

4.2 Pharmacodynamics

Toltrazuril is a triazinon derivative. It acts against coccidia of the genus *Cystoisospora* and *Eimeria*. 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

Piglets

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.

Calves

After oral administration in cattle toltrazuril is slowly absorbed. The maximal plasma concentration (Cmax = 36.6 mg/l) was observed between 24 and 48 hours (geometric mean 33.9 hours) following oral administration. The elimination of toltrazuril is slow with a terminal half-life time of approximately 2.5 days (64.2 hours). The main metabolite is characterised as toltrazuril sulfone. The major route of excretion is *via* the faeces.

Lambs

After oral administration toltrazuril is slowly absorbed in mammals. The main metabolite is characterised as toltrazuril sulfone. The maximal plasma concentration (Cmax = 62 mg/L) was observed 2 days following oral administration. The elimination of toltrazuril is slow with an elimination half-life time of approximately 9 days. The major route of excretion is via the faeces

Environmental properties

The metabolite of toltrazuril, toltrazuril sulfone (ponazuril) is a persistent (half-life >1 year) and mobile compound and has adverse effects on both the growth and emergence of plants. Given the persistent properties of ponazuril repeated spreading of manure from treated animals may lead to an accumulation in the soil and consequently a risk to plants. The accumulation of ponazuril in soil together with its mobility also leads to a risk of leaching to groundwater. See also sections 3.3 and 3.5.

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: 1 year.

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 containing 100 or 250 ml with a high density polyethylene screw cap closure

and

High density polyethylene flexi-pack bottles containing 1 L and 5 L with a polypropylene screw cap closure.

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

Chanelle Pharmaceuticals Manufacturing Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10987/185/001

8. DATE OF FIRST AUTHORISATION

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

07/10/2025

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).