

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

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

Chanox vet 50 mg/ml Oral Suspension for Piglets, Calves and Lambs (Finland, Norway, Sweden)

Cenzuril 50 mg/ml Oral Suspension for Piglets, Calves and Lambs (Spain)

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each ml contains:

**Active substance:**

Toltrazuril	50 mg
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**Excipients:**

Sodium benzoate (E211)	2.1 mg
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Sodium propionate (E281)	2.1 mg
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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), Cattle (calves on dairy farms – see section 4.3) and Sheep (lambs) '

#### **4.2 Indications for use, specifying the 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*.

#### **4.3 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 4.5, other precautions and section 5.3, environmental properties.

#### **4.4 Special warnings for each target species**

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.

#### **4.5 Special precautions for use**

##### i) Special precautions for use in animals

Not applicable.

##### ii) 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.

##### iii) Other precautions

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.

For environmental reasons:

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.

#### **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 interaction**

None known

#### **4.9 Amounts to be administered and administration route**

##### **All Species**

For oral use.

The oral suspension must be shaken before use.

To ensure administration of a correct dose, body weight should be determined as accurately as possible.

To obtain maximum benefit, animals should be treated before the expected onset of clinical signs, i.e. in the prepatent period.

##### **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.

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

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.

#### **4.11 Withdrawal period(s)**

##### **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.

## **5. PHARMACOLOGICAL PROPERTIES**

Pharmacotherapeutic group: Antiprotozoals: triazines; toltrazuril

ATCvet code: QP51AJ01

### **5.1 Pharmacodynamic properties**

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.

### **5.2 Pharmacokinetic particulars**

#### **Piglets**

After oral administration toltrazuril is slowly absorbed with a bioavailability of  $\geq 70\%$ . 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 ( $C_{max} = 36.6 \text{ mg/l}$ ) 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 ( $C_{max} = 62 \text{ mg/L}$ ) 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 4.3 and 4.5.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Sodium benzoate (E211)  
Sodium propionate (E281)  
Citric acid, monohydrate (for pH adjustment)  
Sodium hydroxide (for pH adjustment)  
Xanthan gum  
Aluminium magnesium silicate  
Sodium laurilsulfate  
Propylene glycol  
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: 4 years  
Shelf life after first opening the immediate packaging: 1 year.

### **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 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.

### **6.6 Special precautions for the disposal of unused veterinary medicinal product 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**

Chanelle Pharmaceuticals Manufacturing Ltd.  
Loughrea  
Co. Galway  
Ireland

**8.     MARKETING AUTHORISATION NUMBER**

**9.     DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

**10.   DATE OF REVISION OF THE TEXT**