A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE/IMMEDIATE PACKAGE

{Carton /Label for 100 ml, 250 ml, 1L and 5L bottle}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

toltrazuril

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains 50 mg Toltrazuril

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

100 ml

250 ml

1 L

5 L

5. TARGET SPECIES

Piglets, calves and lambs.

6. INDICATIONS

7. METHOD AND ROUTES OF ADMINISTRATION

For oral use.

Shake well before use.

Read the package leaflet before use.

8. WITHDRAWAL PERIODS

Withdrawal period

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.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Once opened use within 1 year

Once opened use by:

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OF RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder:

Chanelle Pharmaceuticals Manufacturing Ltd.

Loughrea

Co. Galway

Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08749/4071

17. MANUFACTURER'S BATCH NUMBER

BN {number}

PACKAGE LEAFLET

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

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:

Chanelle Pharmaceuticals Manufacturing Ltd.

Loughrea

Co. Galway

Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

Toltrazuril

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Active substance:

Toltrazuril	50.00 mg/ml

Preservatives:

Sodium benzoate (E211)	2.1 mg/ml
Sodium propionate (E281)	2.1 mg/ml

A white to yellowish oral suspension.

4. INDICATION(S)

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*.

5. 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 Special Warning(s).

6. ADVERSE REACTIONS

None known

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 inform your veterinary surgeon. Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Pigs (piglets), Cattle (calves on dairy farms - see section 5) and Sheep (lambs).

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

9. ADVICE ON CORRECT ADMINISTRATION

Shake well before use.

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

10. WITHDRAWAL PERIOD

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.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Shelf life after first opening the container: 1 year.

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 carton after EXP.

The expiry date refers to the last day of that month

12. SPECIAL WARNING(S)

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.

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.

Use during pregnancy and lactation

Not applicable.

Interaction with other medicinal products and other forms of interaction:

None known

Overdose (symptoms, emergency procedures, 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.

Incompatibilities

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

Other precautions and Environmental warnings

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.

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 contraindications.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

April 2022

15. OTHER INFORMATION

Pack sizes: 100 ml, 250 ml, 1 litre, 5 litre.

Not all pack sizes may be marketed.

For Animal Treatment Only. To be supplied only on veterinary prescription.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Approved 10 June 2022