ANNE III

LABELLING AND PACKAGE LEAFLET

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

HDPE bottle/can

1. Name and address of the marketing authorisation holder and of the manufacturing authorisation holder responsible for batch release , if different

Marketing authorisation holder:
Dopharma Research B.V.
Zalmweg 24
4941 VX Raamsdonksveer, NL

Manufacturer responsible for the batch release:
Dopharma France
23, Rue du Prieuré
Saint Herblon
44150 Vair sur Loire, France

Dopharma B.V.
Zalmweg 24
4941 VX Raamsdonksveer, NL

2. Name of the veterinary medicinal product

Dozuril 50 mg/ml oral suspension for pigs
Toltrazuril

3. Statement of the active substance and other ingredients

Each ml contains:
Active substance:
Toltrazuril 50 mg
Excipients:
Sodium benzoate (E211) 2.1 mg
Sodium propionate (E281) 2.1 mg

White or yellowish oral suspension

4. Pharmaceutical form

Oral suspension

5. Package size

250 ml

1000 ml

6. Indication(s)

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 *Isospora suis*.

7. Contraindications

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

8. Adverse reactions

None known.
If you notice any side effects, even those not already listed in this label or you think that the medicine has not worked, please inform your veterinary surgeon.

9. Target species

Pigs (piglets 3 – 5 days old)

10. Dosage for each species, route and method of administration

For oral administration.
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.

11. Advise on correct administration

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.

12. Withdrawal period(s)

Withdrawal period(s):
Pigs (meat and offal): 61 days.

13. Special storage precautions

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.

14. 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 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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
People with known sensitivity to the active substance or any of the excipients should avoid contact with this product.
Avoid skin and eye contact with the product.
Wash any splashes from skin or eyes immediately with water.
Do not eat, drink or smoke while using the product.

Interaction with other medicaments and other forms of interaction
None known, e.g. there is no interaction in combination with iron supplementation

Overdose (symptoms, emergency procedures, antidotes)
No signs of intolerance were observed in piglets up to threefold overdose.

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

15. Special precautions for the disposal of unused products or waste materials, 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.

16. Date on which the package leaflet was last approved

17. Other information

List of pack sizes:
- Bottle of 250 ml
- Bottle of 1000 ml

Not all pack sizes may be marketed.

18. The words "for animal treatment only" and conditions or restrictions regarding supply and use, if applicable

For animal treatment only - to be supplied only on veterinary prescription

19. The words "keep out of the sight and reach of children"

Keep out of the sight and reach of children.

20. Expiry date

EXP << >>

Shelf life after first opening the container: 6 months.

Once opened, use by __/__

21. Marketing authorisation number(s)

22. Manufacturer's batch number

Batch << >>