ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dozuril 50 mg/ml oral suspension for pigs (FR, AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, HR, HU, IE, IT, LT, LU, LV, NL, PL, PT, RO, SK)

Dozuril vet 50 mg/ml oral suspension for pigs (FI, NO, SE)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Toltrazuril 50 mg

Excipients:

Sodium benzoate (E211) 2.1 mg

Sodium propionate (E281) 2.1 mg

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:

Pig (piglets 3-5 days old)

4.2 Indications for use, specifying the 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 *Isospora suis*.

4.3 Contraindications

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

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 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.

4.5 Special precautions for use

Special precautions for use in animals

None.

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.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy and lactation or lay

Not applicable.

4.8 Interactions with other medicinal products and other form of interaction

None known, e.g. there is no interaction in combination with iron supplementation.

4.9 Amounts to be administered and administration route

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.
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.

4.10 Overdose (symptoms, emergency procedures, antidotes)

No signs of intolerance were observed in piglets up to threefold overdose.

4.11 Withdrawal period

Meat and offal: 61 days.

5 PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiparasitic products, insecticides & repellents: Antiprotozoals.
Triazinetrione group
ATCVet Code: QP51AJ01

5.1 Pharmacodynamic properties

Toltrazuril is a triazinon derivative. It acts against coccidia of the genus *Isospora*. 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.

5.2. Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium benzoate (E211)
Sodium propionate (E281)
Sodium docusate
Bentonite

Xanthan Gum (E451)
Propylene glycol (E1520)
Citric acid, anhydrous
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: 6 months

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of the 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.

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 products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Dopharma Research B.V.
Zalmweg 24
4941 VX Raamsdonksveer The Netherlands
research@dopharma.com

8. MARKETING AUTHORISATION NUMBER (S)

9. DATE OF FIRST AUTHORISATION /RENEWAL OF THE AUTHORISATION

Date of first authorisation:
Date of last renewal:

10. DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

Under veterinary prescription