

DATA SHEET (SUMMARY OF PRODUCT CHARACTERISTICS)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PROLCEN VETERINARY

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

Active substance:

Amprolium (hydrochloride) 200 mg

Excipients, q.s.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder for administration in drinking water.

4. CLINICAL DATA

4.1 Target Species

Poultry: chickens (broilers, future laying and reproducing pullets and laying hens) and turkeys.

4.2 Indications for use, specifying the target species

Poultry: For treatment of coccidiosis caused by amprolium-sensitive *Eimeria* spp.

4.3 Contraindications

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

4.4 Special warnings for each target species

Frequent and repeated use of antiprotozoals from the same class or for a long period of time increases the risk of developing a resistance.

4.5 Special precautions for use

Special precautions for use in animals

None.

Specific precautions to be taken by the person administering the veterinary medicinal product to the animals

Persons with known hypersensitivity to amprolium should avoid all contact with the veterinary medicinal product.

Handle the medicinal product with care to avoid inhaling the dust, as well as skin and eyes contact while adding it to the water, and take specific precautions:

- Take appropriate measures to avoid dust release during incorporation of the medicinal product to the drinking water.

- Wear a dust mask (conforming to standard EN140FFP1), gloves, overall and approved safety goggles.

In the event of accidental exposure to the skin or eyes, rinse immediately with abundant water.

Do not smoke, eat or drink while handling the medicinal product.

4.6 Adverse reactions (frequency and seriousness)

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form

<https://sideeffects.health.gov.il>

4.7 Use during pregnancy, lactation or laying
No contraindications described during laying.

4.8 Interaction with other medicinal products and other forms of interaction

Amprolium is an analogue of thiamine. Its administration simultaneously with vitamin B complex could reduce its efficiency.

4.9 Dosage and route of administration

Administration in drinking water.

In all target species the recommended dosage is:

30 mg of amprolium/kg live weight/day (equivalent to 150 mg of medicinal product/kg live weight/day) during 5-7 days.

The preparation of the medicated water must take into account the weight of the animals to be treated and the actual water consumption. Water consumption depends on various factors such as age, clinical status of the animals, breed or farming system.

Based on the recommended dose, the number and weight of birds to be treated, the exact daily dose of medicinal product shall be calculated using the following formula

$$\frac{\text{g of medicinal product}}{\text{litre of drinking water}} = \frac{\text{dose of active substance (mg/kg live weight/day)} \times \text{average animal weight (kg)}}{\text{mg of active substance in g of medicinal product (mg/g)} \times \text{average water consumption (litres/day)}}$$

Medicated water will be the only source of water during treatment; access to medicated water must be ensured for all animals.

4.10 Overdosage (symptoms, emergency procedures, antidotes), if necessary

Prolonged use may cause deficient levels of thiamine. If any symptoms appear, administer thiamine.

4.11. Withdrawal periods

Meat: zero days.

Egg: zero days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiprotozoal

ATCvet code: QP51AX09

5.1 Pharmacodynamic properties

Amprolium is an anticoccidial agent that acts as a competitive inhibitor of thiamine in the parasite metabolism and interferes with the development of the oocysts walls.

5.2. Pharmacokinetic particulars

After oral administration it is absorbed slowly, reaching the maximum concentration after 1-4 hours. It is eliminated mainly in the faeces.

6. PHARMACEUTICAL DATA

6.1 List of excipients

Colloidal anhydrous silica

Lactose monohydrate

6.2 Incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

Shelf life after first opening of the primary packaging: 3 months.

Shelf life following dissolution according to instructions: 24 hours.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Low density polypropylene, aluminium and polyethylene bag, closed by thermosealing.

Formats: 100-kg bag. 1-kg bag.

Not all formats might be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or, if applicable, waste materials derived from the use of such product

Any unused veterinary medicinal product or waste material derived from it should be disposed of according to the local regulations

7. NAME OF THE MARKETING AUTHORISATION HOLDER

M.P.VET LTD,

POB 7004 , PETACH TIKVA 49170

8. MANUFACTURER

Laboratorios CENAVISA, S.A.

Cami Pedra Estela s/n 43205 REUS

Tel.: 977 757 273

Fax: 977 751 398

e-mail: cenavisa@cenavisa.com

8 .MARKETING AUTHORISATION NUMBER

158-89-34655

9 .DATE OF FIRST AUTHORISATION OR DATE OF RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11/07/2017

DATE OF REVISION OF THE TEXT 23/05/2022

PROHIBITION TO SELL, DISPENSE AND/OR USE

Dispensing requirements: **Medicinal product subject to veterinary prescription .**

Administration conditions: **To be administered under veterinary control or supervision.**