

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Brand Name: Piperazine Citrate

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient: Piperazine Citrate, 1000mg/g

3. PHARMACEUTICAL FORM

A white Crystalline or almost white Granular Powder for oral use

4. CLINICAL PARTICULARS

4.1 Target species

Calves, donkeys, horses, pigs, rabbits, dogs, cats and poultry

4.2 Therapeutic indications

Piperazine Citrate is indicated for Nematode infections in horses, swine, cattle and poultry.

Horses: Strongylus, Oxyuris, Trichonema and Ascaris.

Swine: Oesophagostomum and Ascaris.

Cattle: Ascaris, Nematodirus, Ostertagia, Cooperia and Oesophagostomum.

Poultry: Ascaris and Capillaria.

4.3 Contraindications

Whilst piperazine salts have few side effects and are of low toxicity, care should be taken, ensure that the correct dosage is calculated by weighing the animal prior to administration of the drug.

4.4 Special warnings and precautions for use

Undesirable effects, frequency and seriousness Transient neurological effects and urticarial r
Special precautions to be taken by the person administering the product to animals Wash hands immediately after administering the powder reactions have occasionally been noted.

4.5 Use during Pregnancy, Lactation or laying

Consult a veterinary surgeon before treating pregnant animals.

4.6 Interaction with other medicinal products and other forms of interaction

None known

4.7 Posology (dosage) and method of administration

For oral administration: Horses, swine and cattle: 2 - 3 g per 10 kg body weight through drinking water. Poultry: 1g per 1 litre of drinking water for 2 days.

4.8 Overdose

Acute overdose Piperazine has a wide safety margin, and acute overdose is unlikely. Where it does occur however, there may be symptoms of neurotoxicity. There is no known specific antidote. Chronic overdose Piperazine Citrate powder is a single dose treatment. Chronic overdose is therefore not an issue.

4.9 Withdrawal Periods

- For Meat: 2 days
- For Eggs: 1 day

5. PHARMACOLOGICAL PROPERTIES

Summary Presentation of the Active Ingredient

Piperazine Citrate is an anthelmintic of low toxicity with a high efficiency against ascarids and some other nematodes. Pharmacodynamic Properties Piperazine acts to block neuromuscular transmission in the parasite by hyperpolarizing the nerve membrane, which leads to flaccid paralysis. It also blocks succinate production by the worm. The parasites, paralysed and depleted of energy, are expelled by peristalsis. It is active against the ascarids *Toxocara canis*, *Toxocara cati*/ roundworm, *Toxascaris leonine* and hookworms.

Pharmacokinetic Properties

Piperazine is rapidly absorbed from the GI tract, and piperazine base can be detected in the urine as early as 30 minutes after administration. The excretion rate is maximal at 1 – 8hr, and excretion is practically complete within 24hrs.

ATC Vet Code QP52AH01

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None

6.2 Incompatibilities

None known

6.3 Shelf life

3 years

After first opening -28 days

6.4 Special precautions for storage

Protect from light. DO NOT STORE ABOVE 30°C. Store in a dry place.

6.5 Nature and component of immediate packaging

Sachets (laminated paper)

6.6 Special precautions for disposal of unused product or waste materials derived from the use of such products.

Use the local country regulatory agency laid down procedures.

7. MARKETING AUTHORIZATION HOLDER AND MANUFACTURING SITE ADDRESSES

7.1 Marketing authorization holder

VETCARE KENYA LTD

Address: P.O Box 63405 – 00619 Nairobi

Country: Kenya

7.2 Manufacturing site addresses

VETCARE KENYA LTD

Winsford Park, BabaDogo Road

P.O. BOX 63405 00619 Nairobi, Kenya

7.3 Marketing Authorization Number

Rwanda FDA-VMP-MA-0001

7.4 Date of first Authorization/renewal of the Authorization

Date of first Authorization in Rwanda: 9th August 2021

7.5 Date of revision of the text

11th April 2022