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# **Summary of Product Characteristics**

# 1 Name of the veterinary medicinal product.

Piperazine Citrate Tablets BP 500mg

#### 2. Qualitative and quantitative composition.

Each tablet contains:

For a full list of excipients, see section 6.1

# 3. Pharmaceutical form.

Tablet

White Circular, biconvex, tablets. Scored on one side.

#### 4. Clinical particulars.

#### 4.1 Target species;

Dogs and cats

#### 4.2 Indications for use, specifying the target species;

For the treatment of Roundworms (Ascarids) and Hookworms in both dogs and cats.

#### 4.3 Contra indication:

Do not give more than 6 tablets in any one dose. If no vomiting occurs the remaining dose may be given after 3 hours.

Do not repeat the treatment if vomiting occurs shortly after dosing.

Do not administer to puppies or kittens weighing less than 1.25Kg.

#### 4.4 Special warnings for each target species;

None

#### 4.5 Special precautions for use.

#### i) Special precautions for use in animals

Consult a veterinary surgeon before dosing animals with a history of epilepsy or severe renal dysfunction.

Do not use if your pet is sick or recovering from an illness.

Animals weighing less than 1.25Kg should be treated with a suitable product authorised for this purpose.

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# ii) Special precautions to be taken by the person administering the medicinal product to animals

Wash hands immediately after handling the tablets.

Accidental eye contact – rinse thoroughly with clean running water. If irritation persists seek medical advice.

Accidental ingestion by humans – drink plenty of water and seek medical advice.

#### 4.6 Adverse reactions (frequency and seriousness);

None reported

#### 4.7 Use during pregnancy, lactation or lay;

Not applicable.

# 4.8 Interaction with other medicinal products and other forms of interaction;

**Interaction with medicinal products** – None known. **Other** - None known.

#### 4.9 Amounts to be administered and administration route;

The tablets are best administered immediately before the main feed of the day and may be given whole or crushed and given in food. To ensure administration of a correct dose, body weight should be determined as accurately as possible. Adult animals should be treated every 3 months.

Repeat the dose in 14 days

Dosage: Administer one tablet per 2.5Kg body weight or ½ tablet per 1.25Kg. Puppies and kittens should be treated at 2 weeks of age until 12 weeks of age. Thereafter they should be treated at 3 monthly intervals. Nursing females should be dosed 2 weeks after giving birth and every 2 weeks until weaning. It is advisable to treat the female at the same time as the puppies or kittens.

# 4.10 Overdose (symptoms, emergency procedures, antidotes) if necessary;

Overdose may cause vomiting, diarrhoea and ataxia in dogs and cats.

#### 4.11 Withdrawal period(s);

Not applicable

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# 5. Pharmacological Properties.

# 5.1 Pharmacodynamic properties;

Anthelmintic – The antiparasitic properties of Piperazine Citrate and the other piperazine salts used as anthelmintics depends almost solely on the piperazine base. The material has a narcotising and paralytic effect on the worms which lose their mobility and thus their ability to maintain their position in the gastrointestinal tract. This allows them to be swept along and be voided in the faeces. This effect is evident after a few hours after dosing. The use of a purgative is not a recommended part of treatment as it may speed up the removal of piperazine from the intestinal tract allowing narcotised worms to recover and re-establish a position in the gut. Mature worms are more susceptible to the action of Piperazine than younger stages; hence the requirement to re-treat in 14 days to have an action on newly matured worms before they begin to lay eggs.

#### 5.2 Pharmacokinetic properties;

Piperazine salts are readily absorbed from the gastrointestinal tract. Up to 40% is excreted in the urine after 2 to 3 days. The majority is excreted in the bile.

# 6 Pharmaceutical particulars

# 6.1 List of excipients;

Lactose Monohydrate Gelatin, Hydrolysed Magnesium Stearate Hydrogenated Castor oil Talc, Purified

#### 6.2 Incompatibilities;

Not applicable

#### 6.3 Shelf life;

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

# 6.4 Special precautions for storage.

Do not store above 25°C Protect from light.
Any part used tablets should be discarded.

#### 6.5 Nature and composition of immediate packaging.

6 or 24 tablets packed in white cylindrical HDPE containers with a white HDPE lid. Not all pack sizes may be marketed.

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# 6.6 Special precautions for disposal of unused veterinary medicinal products 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. Authorisation holder.

Battle, Hayward and Bower Ltd Crofton Drive, Lincoln. LN3 4NP

# 8. Marketing Authorisation Number

Vm 00676/4104

# 9. Date of the first authorisation

13th December 1995

# 10. Date of revision of the text

December 2008