Revised: 20th January 2009

AN: 02296/2007

# **Summary of Product Characteristics**

#### 1 Name of the veterinary medicinal product.

Dichlorophen Tablets BP 500mg

### 2. Qualitative and Quantitative Composition.

Each tablet contains:

Active substance(s) mg
Dichlorophen 500.0

**Excipient(s)** 

Amaranth (E123) 0.055

For a full list of excipients see section 6.1

#### 3. Pharmaceutical form.

**Tablet** 

Circular, biconvex, pink tablets. Engraved with a breakline 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 tapeworms, <u>Taenia spp</u> and <u>Dipylidium spp</u>, in dogs and cats over 6 months old.

#### 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 animals weighing less than 1.25Kg or under 6 months of age.

Do not repeat the treatment in less than 10 days.

# 4.4 Special warnings for each target species;

Cats are particularly susceptible to CNS side effects of phenols which include vomiting, depression and incoordination.

#### 4.5 Special precautions for use.

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

Do not exceed the recommended dosage.

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.

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

Wash hands after handling tablets.

In case of accidental eye contact – rinse thoroughly with clean running water. If irritation persists seek medical advice.

In case of accidental ingestion – drink plenty of water and seek medical advice.

# 4.6 Adverse reactions (frequency and seriousness);

Dogs – None reported

Cats – Cats are particularly susceptible to CNS side effects of phenols which include vomiting, depression and incoordination.

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

Consult a veterinary surgeon before dosing pregnant animals.

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

**Interaction with medicinal products** – None reported.

Other – None reported

# 4.9 Amounts to be administered and administration route;

Fasting before, or the administration of a purgative after, dosing is unnecessary with this product. The tablets are best administered immediately before the main feed of the day and may be given whole or crushed and given in food.

Dosage: administer one tablet per 2.5kg bodyweight. Administer ½ a tablet for bodyweight less than 2.5kg

Animals should be treated every 4-6 months.

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

Symptoms include vomiting, depression and in-coordination. There is no known antidote. Treatment should be symptomatic.

#### 4.11 Withdrawal period(s)

Not applicable

#### 5. Pharmacological Properties.

ATCvet Code: QP52AG01

# 5.1 Pharmacodynamic properties;

Dichlorophen has antimicrobial and anthelmintic properties which are effective against <u>Taenia spp</u> and <u>Dipylidium spp</u> but not against <u>Echinococcus spp</u> tapeworms. Shortly after dosing the tapeworm detaches itself from the wall of the intestine and is killed, partially digested and excreted in the faeces. Dichlorophen reacts with drug receptors in the parasite and not with host receptors.

#### 5.2 Pharmacokinetic properties;

There is little absorption of dichlorophen as it passes through the gastrointestinal tract leaving most of the drug to be available at the desired site of reaction. The drug is then flushed out of the body during normal bodily functions.

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# **6 Pharmaceutical particulars**

### 6.1 List of excipients;

Amaranth (E123) Gelatin, Hydrolysed Magnesium Stearate Maize Starch 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.

# 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 product 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 00676/4103

#### 9. Date of the first authorisation

17th November 1995

#### 10. Date of revision of the text

January 2009