#### **SUMMARY OF PRODUCT CHARACTERISTICS**

#### 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Beaphar Multiwormer for Dogs, Tablets

#### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

#### Tapeworm tablets (fawn)

Active substance	<u>mg/tablet</u>
Dichlorophen	750.00
Excipients	mg/tablet
Caramel 15712 (E150)	12.15

For full list of excipients, see section 6.1

#### Roundworm tablets (pink)

Active substance	mg/tablet
Piperazine Citrate	375.00
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Excipients	mg/tablet
Erythrosine Lake (E127)	1.425

For full list of excipients, see section 6.1

#### 3. PHARMACEUTICAL FORM

**Tablets** 

Roundworm tablet: Slightly mottled pink, circular bi-convex tablet embossed with a

break-line on one face.

Tapeworm tablet: Mottled fawn to off-white, circular flat faced bevel edged tablet.

#### 4. CLINICAL PARTICULARS

#### 4.1 Target species

Dogs over 6 months of age

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

For the treatment of roundworm (Ascarids) and tapeworm infections in dogs over six months old

#### 4.3 Contra-indications

Do not treat dogs under 1.9 kg (4lb) or less than 6 months old.

#### 4.4 Special warnings for each target species

Do not treat dogs under 1.9 kg (4 lb), or less than 6 months old.

Do not repeat treatment if dog vomits after administration.

Do not administer more than 6 tablets in a single dose. If no vomiting occurs, the remaining dose may be administered after 3 hours.

#### 4.5 Special precautions for use

i. Special precautions for use in animals

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

It is important to establish the bodyweight of the animal before treatment to ensure correct dosage administration.

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

Wash hands thoroughly after handling 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)

Dichlorophen may cause vomiting in sensitive dogs.

Large numbers of tablets given concurrently may cause vomiting in some dogs.

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

Consult a veterinary surgeon before treating pregnant animals.

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

None known

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

For oral administration

Treatment consists of three doses given at weekly intervals. Administer one pink tablet per 3.8 kg (8.5 lb) bodyweight on day 1, then one fawn tablet per 3.8 kg on day 8, and one pink tablet per 3.8 kg on day 15. Tablets may be taken whole, or crushed and sprinkled on the dog's food. Do not remove tablets from strip until required for treatment.

Dogs should be treated every 3 months.

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

<u>Piperazine Citrate</u> <u>Dichlorophen</u>

Symptoms: Vomiting and diarrhoea Vomiting

Depression General weakness

Ataxia and muscle weakness Ataxia

Fits

Emergency Procedures: Consult a veterinary surgeon.

Treat symptomatically and supportively.

Keep animal warm and calm.

Symptoms reverse in 24 - 48 hours

#### 4.11 Withdrawal period(s)

Not applicable

#### 5. PHARMACOLOGICAL PROPERTIES

ATCvet codes: QP52AG01, QP52AH01

#### 5.1 Pharmacodynamic properties

Piperazine acts as an anthelmintic by causing nerve paralysis of the worm, with subsequent expulsion.

Dichlorophen is effective against most common cestodes, and also has antibacterial and antifungal properties.

#### 5.2 Pharmacokinetic particulars

The citrate is quickly absorbed in the dog and excreted in the urine.

#### 6. PHARMACEUTICAL PARTICULARS

#### 6.1 List of excipients

Tapeworm tablets (fawn)
Caramel 15712 (E150)
Pregelatinised Starch
Maize Starch
Magnesium Stearate

Roundworm tablets (pink)
Erythrosine Lake (E127)
Cellulose Microcrystalline
Magnesium Stearate
Silica Colloidal Anhydrous

#### 6.2 Incompatibilities

None known.

#### 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.

Do not remove tablets from strip until required for treatment Any part-used tablets should be discarded.

#### 6.5 Nature and composition of immediate packaging

8 or 24 pink roundworm tablets and 4 or 12 fawn tapeworm tablets in the following packs:

Container: PVC – aluminium foil blister strip

Closure: Heat – seal

Secondary pack: One blister of 8 roundworm tablets with one blister of 4

fawn tapeworm tablets per carton

One blister of 24 roundworm tablets with one blister of 12

fawn tapeworm tablets per carton

OR

Three blisters of 8 roundworm tablets with three blisters of 4 fawn tapeworm tablets per carton

Not all pack sizes may be marketed.

# 6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products, if appropriate

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

Beaphar UK Ltd Rook Tree Farm Withersfield Road Great Wratting Suffolk CB9 7HD

#### 8. MARKETING AUTHORISATION NUMBER

Vm 13907/4011

## 9. DATE OF FIRST AUTHORISATION

21 September 1994

### 10. DATE OF REVISION OF THE TEXT

June 2018

Approved: 07 June 2018

D. Auster