

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Veterinary Medicinal Product:

Johnson's Easy Round-Wormer for Puppies and Dogs 416mg tablet

2. Qualitative and Quantitative Composition:

Active substance

Piperazine Phosphate 416mg per tablet.

Excipient

Amaranth Lake (E123) 0.75 mg per tablet

Amaranth (E123) 0.3 mg per tablet

For full list of excipients, see section 6.1.

3. Pharmaceutical form:

Tablet.

Pink biconvex circular $\frac{9}{16}$ " tablet with $\frac{1}{4}$ -breakline one side.

4. Clinical particulars:

4.1 Target species:

Puppies over 2 weeks of age and adult dogs.

4.2 Indications for use, specifying the target species:

Roundworm treatment for the control of ascarids (Toxocara and Toxascaris).

4.3 Contra-Indications:

Do not use on puppies under 2 weeks of age.
Do not use on very small animals.

4.4 Special warnings for each target species:

None stated.

4.5 Special precautions for use:

4.5 i) Special precautions for use in animals:

Do not exceed the stated dose.

Do not administer more than 6 tablets as single dose in large dogs - remainder of dose should be administered after 3 hours if no vomiting has occurred.

Do not repeat treatment if vomiting occurs shortly after dosing.

It is advisable to consult a veterinary surgeon before treating animals with a history of epilepsy and kidney disease.

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

Wash hands 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)

None stated.

4.7 Use during pregnancy, lactation or lay:

It is advisable to consult a veterinary surgeon before treating pregnant animals.

Pregnant Bitches should be dosed at 3 weeks and 1 week before giving birth. Nursing Bitches should be dosed 2 weeks after giving birth and every 2 weeks until weaning. It is advisable to treat the bitch at the same time as the puppies.

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

None reported.

4.9 Amounts to be administered and administration route:

ACCURATE WEIGHING OF THE ANIMAL PRIOR TO DOSING IS ESSENTIAL.

ROUNDWORM TREATMENT FOR DOGS & PUPPIES OVER 2 WEEKS OF AGE, WITH MINIMUM BODYWEIGHT OF 1.0kg (2¼ lb)

Less than 0.25kg (½lb)	Consult a Veterinary Surgeon
0.25 to 1.0 kg (½ - 2¼ lb)	Use a syrup formulation
1.1 to 2.5 kg (2½ - 5 lb)	½ tablet
2.6 to 3.7 kg (6 - 8 lb)	¾ tablet
3.8 to 5.0 kg (9 -11 lb)	1 tablet
5.1 to 7.5 kg (12 - 16 lb)	1½ tablets
7.6 to 10.0 kg (17 - 22 lb)	2 tablets
10.1 to 15.0 kg (23 - 33 lb)	3 tablets
15.1 to 20.0 kg (34 - 44 lb)	4 tablets
20.1 to 25.0 kg (45 - 55 lb)	5 tablets
25.1 to 30.0 kg (56 - 66 lb)	6 tablets
30.1 to 35.0 kg (67 - 77 lb)	7 tablets
35.1 to 40.0 kg (78 - 88 lb)	8 tablets

For larger dogs, give 1 extra tablet for each additional 4kg (8.8lb) bodyweight. Do not administer more than 6 tablets as a single dose in large dogs. Remaining dose should be administered after 3 hours if no vomiting has occurred.

Give the number of tablets as above immediately before a normal meal. Puppies and dogs will often eat these tasty tablets from the hand. Otherwise, crush and mix in a little tasty food or give whole followed by a drink. If animal is difficult to dose, reduce previous meal so that animal is hungry before dosing. Repeat the same dose in 14 days' time.

Do not repeat treatment if vomiting occurs shortly after dosing. Keep animals under observation for one hour after dosing to ensure that tablets are ingested. Any part-used tablets should be discarded.

Puppies should be treated for roundworms at 2 weeks of age and every 2 weeks until 12 weeks of age; thereafter they should be treated at 3 month intervals. Pregnant Bitches should be dosed at 3 weeks and 1 week before giving birth. Nursing Bitches should be dosed 2 weeks after giving birth and every 2 weeks until weaning. It is advisable to treat the bitch at the same time as the puppies.

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

None stated.

4.11 Withdrawal periods:

Not applicable.

5. Pharmacological properties:

ATC Vet code: QP52AH01

5.1 Pharmacodynamic properties:

Various salts of Piperazine are used widely for the control of ascarid intestinal worms in dogs and cats.

Anthelmintic activity of Piperazine and its derivatives depends on their anticholinergic action at the myoneural junction in worms and causes a hyperpolarization, neuro-muscular block. Succinic acid production by the worm is also blocked. These actions result in a narcotizing or (flaccid) paralytic effect. The worms lose motility and thus their ability to maintain position in the gastrointestinal tract. This allows them to be passively swept along by peristalsis and be voided live in faeces. If the drug is quickly voided by the host, for example if a purgative accompanies drug administration, then a narcotized worm may regain its motility and re-establish a position in the gut. Therefore, purgation is not generally advised when Piperazine is used.

Mature worms are more susceptible to the action of Piperazine than younger stages. Lumen-dwelling larvae and immature adults are sufficiently susceptible to be at least partially eliminated. Larval stages in host tissues, especially larvae that are moulting are little affected by the drug. Therefore, treatments are often repeated two weeks later. In dogs and cats, the action of Piperazine is up to 100% efficient against *Toxocara* and *Toxascaris* species and up to 75% effective against hookworms. The drug has practically no effect on whipworms (*Trichuris* species) and on tapeworms.

5.2 Pharmacokinetic particulars:

No other information available.

6. Pharmaceutical particulars:

6.1 List of excipients:

Amaranth Lake (E123)
Amaranth (E123)
Monosodium Glutamate Monohydrate
Edible Bone Phosphate
Sucrose Powdered
Pregelatinised Starch
Lactose Monohydrate
Calcium Hydrogen Phosphate Anhydrous
Stearic Acid
Beef Flav-o-lok 610398E
Magnesium Stearate
Sodium Starch Glycollate

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.
Store in a dry place.
Protect from light.

6.5 Nature and composition of immediate packaging:

Pack Size: 8 tablets

A) Container: Clear colourless regenerated cellulose/polyurethane/
polyethylene laminate strip-pack.
Closure: Heat seal.

B) Container: Clear colourless polyvinylchloride/polyvinylidene
chloride
blister pack.
Closure: Aluminium foil.

Secondary packaging: Solid board carton.

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.

7.0 Marketing Authorisation holder:

Johnson's Veterinary Products Ltd
5 Reddicap Trading Estate
Sutton Coldfield
West Midlands B75 7DF

8. Marketing Authorisation number(s):

Vm01759/4056

9. Date of first Authorisation:

24.03.95

10. Date of revision of the text:

28.08.08