

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Johnson's Easy Roundwormer for Kittens & Cats 104mg film-coated tablet.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance

Piperazine Phosphate 104mg per tablet

Excipients

Opadry White 03M28781 4.61mg per tablet

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film coated tablet.

White biconvex circular tablet.

4. CLINICAL PARTICULARS

4.1 Target species

Kittens over 2 weeks of age and adult cats.

4.2 Indications for use, specifying the target species

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

4.3 Contra-Indications

Do not use on kittens under 2 weeks of age, or animals under 0.6 kg.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

i Special precautions for use in animals:

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

Do not exceed the stated dose.

Do not repeat treatment if vomiting occurs shortly after dosing.

- 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 reported.

4.7 Use during pregnancy, lactation or lay

It is advisable to consult a veterinary surgeon before treating pregnant animals. Pregnant females should be dosed at 3 weeks and 1 week before giving birth. Nursing females should be dosed 2 weeks after giving birth and every 2 weeks until weaning. It is advisable to treat the adult female at the same time as the kittens.

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 CATS & KITTENS OVER 2 WEEKS OF AGE, WITH MINIMUM BODYWEIGHT OF 0.6kg (1½lb)

Less than 0.25kg (½lb)	Consult a Veterinary Surgeon
0.25 to 0.5 kg (½ - 1 lb)	Use a syrup formulation
0.6 to 1.2 kg (1½ - 2½ lb)	1 tablet
1.3 to 2.5 kg (3 - 5 lb)	2 tablets
2.6 to 3.7 kg (6 - 8 lb)	3 tablets
3.8 to 5.0 kg (9 -11 lb)	4 tablets
5.1 to 6.3 kg (12 - 14 lb)	5 tablets
6.4 to 7.5 kg (15 - 17 lb)	6 tablets

Give the number of tablets as above immediately before a normal meal. Slip tablet on to back of tongue, hold mouth closed and gently stroke neck until swallowed. The tablets may be smeared with butter for easier administration. 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.

Kittens 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. Adult cats are also prone to roundworm infestation, in which case dose as above.

Pregnant females should be dosed at 3 weeks and 1 week before giving birth.

Nursing females should be dosed 2 weeks after giving birth and every 2 weeks until weaning. It is advisable to treat the adult female at the same time as the kittens.

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

Film Coating: Opadry White 03M28781**
Glycerol

**Composition of Opadry White 03M28781
Hypromellose
Titanium Dioxide (E171)
Glycerol

Tablet Cores: Icing Sugar
Pregelatinised Starch
Acacia
Calcium Hydrogen Phosphate Anhydrous
Stearic Acid
Magnesium Stearate
Silicon Dioxide
Croscarmellose Sodium

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: 12 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. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER(S)

Vm 01759/4057

9. DATE OF FIRST AUTHORISATION

24.03.95

10. DATE OF REVISION OF THE TEXT

01.07.10