Revised 10 September 2008
AN:00250/2008

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Veterinary Medicinal Product:

Johnson's Puppy Easy Worm Syrup, 4% w/v

2. Qualitative and Quantitative Composition:

Active substance

Qualitative compositon	Quantitative composition % w/v
Piperazine Hexahydrate	4.00

Excipients

Isopropyl alcohol	3.96

For full list of excipients, see section 6.1.

3. Pharmaceutical form:

Syrup.
Clear, straw coloured, slightly viscous liquid with odour characteristic of chocolate.

4. Clinical particulars:

4.1 Target species:

Puppies over 2 weeks of age and with minimum bodyweight of 0.25kg, and nursing bitches.

4.2 Indications for use, specifying the target species:

Treatment for roundworms in puppies over 2 weeks of age and nursing bitches.

4.3 Contra-Indications:

Do not use on puppies under 2 weeks of age and less than 0.25kg bodyweight.
Do not use if your puppy is sick or recovering from an illness.

4.4 Special warnings for each target species:

Vomiting, diarrhoea and/or ataxia may occur if dosage is exceeded.

4.5 i) Special precautions for use in animals:

Accurate dosing is essential and the bodyweight should be determined before calculating dosage.
Do not exceed the stated dose.
Do not repeat if vomiting occurs shortly after dosing.

It is advisable to consult a Veterinary Surgeon before treating pregnant animals and those with a history of epilepsy or disease of the liver or kidneys.

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

Avoid contact with skin and eyes. In case of accidental skin or eye contact, wash the affected area with plenty of water. If irritation persists, seek medical advice.
In case of accidental ingestion by humans, drink plenty of water and seek medical attention.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None reported.

4.7 Use during pregnancy, lactation or lay:

Nursing bitches should be dosed 2 weeks after giving birth and every 2 weeks until weaning. It is advisable to treat bitches at same time as puppies.

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

None reported.

4.9 Amounts to be administered and administration route:

Dogs & Puppies with minimum bodyweight of 0.25kg (½ lb).

Shake well before use. Give before or during a main meal or add to a small portion of tasty food. Give at the rate of 1ml for every ½ kg (1.1 lb) bodyweight as per table below, using plastic measuring cup provided, which must be washed immediately after use.

Less than 0.25kg (½ lb) – Consult a Veterinary Surgeon	
0.25 to 0.5 kg (½ - 1 lb)	1ml
0.6 to 1.0 kg (1½ - 2 lb)	2ml
1.1 to 1.5 kg (2 - 3 lb)	3ml
1.6 to 2.0 kg (3 - 4 lb)	4ml
2.1 to 2.5 kg (4 - 5 lb)	5ml
2.6 to 5.0 kg (5 - 11 lb)	10ml
5.1 to 7.5 kg (11 - 16 lb)	15ml

Repeat above dose in 14 days' time.

Do not repeat treatment if vomiting occurs shortly after dosing.

Puppies over 0.25kg should be treated at 2 weeks of age and every 2 weeks until 12 weeks of age. Thereafter they should be treated at 3 months intervals. 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:

Vomiting, diarrhoea and/or ataxia are reported signs. Treatment is symptomatic.

4.11 Withdrawal periods:

Not applicable.

5. Pharmacological properties:

ATC Vet code: QP52AH01

5.1 Pharmacodynamic properties:

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

Chemically, Piperazine is diethylene diamine. The hexahydrate is physically unstable being very deliquescent, and consequently the drug is used in the form of the more stable salts. The adipate, citrate, hydrochloride, phosphate, sulphate and tartrate salts are white crystalline powders with a saline taste and are readily soluble in water except the insoluble phosphate and the colourless adipate, which dissolve slowly to a maximum of 5% in water.

The antiparasitic activity of various salts of Piperazine depends almost solely on the Piperazine base. The quantity of base varies between the different salts.The hexahydrate contains 44% base. Dosages of the salts of Piperazine are often expressed in terms of the hydrate equivalent: 100mg Piperazine hydrate is equivalent approximately to 120mg Piperazine adipate, to 125mg Piperazine citrate and to 104mg Piperazine phosphate.

Anthelmintic activity of Piperazine and its derivatives depends on their anticholinergic action at the myoneural junction in worms and causes a hyperpolarization, neuromuscular 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, 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% efficient against hookworms. The drug has practically no effect on whipworms (Trichuris species) and on tapeworms.

In ordinary circumstances, the drug is non-toxic.

5.2 Pharmacokinetic particulars:

No other information available.

6. Pharmaceutical particulars:

6.1 List of excipients:

Isopropyl alcohol
Chocolate flavour
Ethanol 96%
Carmellose sodium
Saccharin sodium anhydrous
Water purified

6.2 Incompatibilities:

None known.

6.3 Shelf-life:

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 3 months

6.4 Special precautions for storage:

Do not store above 25°C.
Protect from light.
Following withdrawal of the first dose, use the product within three months.

6.5 Nature and composition of immediate packaging:

50ml, amber, Type III glass bottle with a polypropylene cap (screw-fit) and a graduated translucent, 1-6ml cup.

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):

01759/4061

9. Date of first Authorisation:

06.03.96

10. Date of revision of the text:

10.09.08