

JOHNSON'S VETERINARY PRODUCTS LTD
SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Veterinary Medicinal Product:

Johnson's Easy Wormer Granules for Puppies and Small Dogs 222.22mg

2. Qualitative and Quantitative Composition:

Fenbendazole 222.22 mg/sachet

For full list of excipients, see section 6.1.

3. Pharmaceutical form:

Granules.
White or yellowish-white granular powder.

4. Clinical particulars:

4.1 Target species:

Domestic puppies and small dogs.

4.2 Indications for use, specifying the target species:

For the routine treatment of domestic puppies and small dogs infected with common roundworms of the gastro-intestinal tract.

This product is only for use in puppies weighing a minimum of 2kg (4.4lb) bodyweight and small dogs weighing a minimum of 1kg (2.2lb), smaller or unweaned animals should be treated with a suitable authorised product.

4.3 Contra-Indications:

Do not administer this product to pregnant bitches.

4.4 Special warnings for each target species:

Not for use in puppies weighing less than 2.2kg (4.4lb) bodyweight, or adult dogs weighing less than 1kg (2.2lb) bodyweight.

4.5 Special precautions for use:

4.5 i) Special precautions for use in animals:

Assess bodyweight as accurately as possible before calculating the dosage.

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

Direct contact with the skin should be kept to a minimum.
Avoid inhalation of granule dust.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None reported.

4.7 Use during pregnancy, lactation or lay:

Do not administer this product to pregnant bitches.

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

None known.

4.9 Amounts to be administered and administration route:

Routine treatment of adult dogs

Administer 100mg fenbendazole per 1kg (2.2lb) bodyweight as a single dose.

Each 1g sachet /dose treats 2kg (4.4lb) bodyweight as a single dose (1.1 – 2.2kg)

For dogs weighing over 6kg (13lb), additional sachets are required according to the additional bodyweight.

Assess bodyweight as accurately as possible. The dose should be administered by mixing into the feed.

Treatment should be repeated when natural re-infection with parasitic worms occurs. Routine treatment of adult animals with minimal exposure to infection is advisable 2 to 4 times per year. More frequent treatment, at 6 to 8 weekly intervals is advisable for dogs in kennels.

Weaned puppies under 6 months of age

This product is only for use in puppies weighing a minimum of 2kg (4.4lb) bodyweight, smaller or unweaned puppies should be treated with a suitable authorised product.

Administer 50mg fenbendazole per 1kg (2.2lb) bodyweight daily for 3 consecutive days.

Practical dosage recommendations:

Each 1g sachet/dose treats 4kg (8.8lb) bodyweight (minimum weight 2.2kg) dose daily for 3 consecutive days (2.2 – 4.8kg)

For puppies weighing over 4kg (8.8lb), additional sachets are required according to the additional bodyweight.

Assess bodyweight as accurately as possible. The dose should be administered by mixing into the feed.

Puppies should be treated for roundworms at 2 weeks of age, 5 weeks of age and again before leaving the breeder's premises. Treatment may also be required at 8 and 12 weeks of age. Thereafter, frequency of treatment can be reduced unless the puppies remain in kennels where re-infection occurs more readily.

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

Benzimidazoles have a wide safety margin.

4.11 Withdrawal periods:

Not applicable.

5. Pharmacological properties:

ATC Vet code: QP52AC13

5.1 Pharmacodynamic properties:

Fenbendazole is an anthelmintic belonging to the benzimidazole carbamates group. It acts by interfering in the energy metabolism of the nematode. The anthelmintic efficacy is based on inhibition of the polymerisation of tubulin to microtubuli. The anthelmintic affects both adult and immature stages of gastro-intestinal and respiratory nematodes.

Fenbendazole is only partly absorbed after oral administration and is then metabolised in the liver. The half-life of fenbendazole in serum after oral application of the recommended dose in cattle is 10-18 hours, in sheep 21-33 hours and in pigs 10 hours. Fenbendazole and its metabolites are distributed throughout the body and high concentrations can be found in the liver. The elimination of fenbendazole and its metabolites occurs primarily via the faeces (>90%) and to a small extent in the urine and milk.

Fenbendazole is metabolised to its sulphoxide, then to sulphone and amines.

5.2 Pharmacokinetic particulars:

No other information available.

6. Pharmaceutical particulars:

6.1 List of excipients:

Lactose monohydrate
Povidone 2500
Maize starch

6.2 Incompatibilities:

None known.

6.3 Shelf-life:

Shelf life of the veterinary medicinal product as packaged for sale: 5 years.

6.4 Special precautions for storage:

No special precautions for storage.

6.5 Nature and composition of immediate packaging:

Pack Size: 1.0g of granules.
Container: Low-density polyethylene/aluminium foil/paper laminated sachet.
Closure: Heat seal.

Secondary packaging: Solid board carton containing 3 x 1.0g sachets

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):

Vm01759/4073

9. Date of first Authorisation:

08.01.03

10. Date of revision of the text:

15.07.08