PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{CARTON FOR PACK SIZES OF 2 TABLETS}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Johnsons One Dose Wormer 230/20 Film-Coated Tablets for Cats and Kittens
pyrantel embonate, praziquantel

2. STATEMENT OF ACTIVE SUBSTANCES

Each film-coated tablet contains Pyrantel Embonate 230 mg and Praziquantel 20 mg.

3. PHARMACEUTICAL FORM

Film-coated tablet

4. PACKAGE SIZE

2 tablets

5. TARGET SPECIES

6. INDICATION(S)

For the treatment of mixed infections caused by gastrointestinal roundworms and tapeworms in Cats.

7. METHOD AND ROUTE(S) OF ADMINISTRATION DOSAGE:

The recommended dose is: 20 mg/kg pyrantel (57.5 mg/kg pyrantel embonate) and 5 mg/kg praziquantel. 1 tablet per 4kg bodyweight.

Body weight	tablets
1.0 - 2.0 kg	½
Greater than 2.0 up to 4.0 kg	1
Greater than 4.0 up to 6.0 kg	1 ½
Greater than 6.0 kg	2

Single oral administration.

The tablet should be given directly to the cat, but if necessary can be disguised in food. In ascarid infestation, especially in kittens, complete elimination cannot be expected, so a risk of infection for humans can persist. Repeat treatments should, therefore, be carried out with a suitable roundworm product at 14 day intervals until 2-3weeks after weaning.
Read the package leaflet before use. Keep blister in outer carton. Do not remove tablets from strip packaging until require for use. Unused halved tablets should be discarded.

8. WITHDRAWAL PERIOD

N/A

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use

10. EXPIRY DATE

EXP {month/year}
Unused half tablets should be discarded.
Do not use after expiry date.

11. SPECIAL STORAGE CONDITIONS

Do not remove tablets from blister until required for use.
Keep blister in outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USEIF APPLICABLE*[Distribution category]*

For animal treatment only

AVM-GSL

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

C&H Generics Ltd
c/o Michael McEvoy and Co
Seville House
New Dock Street
Galway
Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 40162/4007

17. MANUFACTURER’S BATCH NUMBER

BN{number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT
Johnsons One Dose Wormer 230/20 Film-Coated Tablets for Cats and Kittens
pyrantel embonate, praziquantel

2. NAME OF THE MARKETING AUTHORISATION HOLDER
C & H Generics Ltd.

3. EXPIRY DATE
EXP {month/year}
4. BATCH NUMBER
BN {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"
For animal treatment only
For oral use

PACKAGE LEAFLET FOR:

Johnsons One Dose Wormer 230/20 film-coated Tablets for Cats and Kittens

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
C&H Generics Ltd
c/o Michael McEvoy and Co
Seville House
New Dock Street
Galway
Ireland

Manufacturer responsible for batch release:
Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co. Galway
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Johnsons One Dose Wormer 230/20 Film-Coated Tablets for Cats and Kittens
pyrantel embonate, praziquantel

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Each film-coated tablet contains Pyrantel embonate 230 mg and Praziquantel 20 mg.
A white to off white round, biconvex coated tablet with a breakline on one side and plain on the other side.

4. INDICATION(S)

For the treatment of mixed infections caused by the following gastrointestinal roundworms and tapeworms.
Roundworms: *Toxocara cati, Toxascaris leonina.*
Tapeworms: *Dipylidium caninum, Taeniataeniae formis, Echinococcus multilocularis.*

5. CONTRAINDICATIONS

Do not use simultaneously with products containing Piperazine. Do not use simultaneously with other deworming products without veterinary advice. Do not use in kittens less than 6 weeks of age. Do not use in animals with known hypersensitivity to the active substances or to any of the excipients.
Do not use during pregnancy.

6. ADVERSE REACTIONS

Mild and short-lived digestive tract disorders such as excessive salivation and/or vomiting and mild and short-lived disorders of the nervous system such as loss of balance may occur in extremely rare cases.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cats

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dosage
The recommended dose is: 20 mg Pyrantel (57.5 mg/kg Pyrantel embonate) and 5 mg/kg Praziquantel. This is equivalent to 1 tablet per 4kg bodyweight.

Practical dosage recommendations:

Weight of cat kgs	lbs	Single dose required
1kg - 2kg	2.2lb - 4.4lb	½ tablet
>2kg - 4kg	>4.4lb - 8.8lb	1 tablet
>4kg - 6kg	>8.8lb - 13.2lb	1½ tablets
>6kg+	>13.2lb+	2 tablets

Administration and duration of treatment

Single oral administration. The tablet should be given directly to the cat, but if necessary can be disguised in food. In ascarid infestation, especially in kittens,

complete elimination cannot be expected, so a risk of infection for humans can persist. Repeat treatments should, therefore, be carried out with a suitable roundworm product at 14 day intervals until 2-3 weeks after weaning. If signs of disease persist or appear, consult a veterinary surgeon.

9. ADVICE ON CORRECT ADMINISTRATION

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible.

10. WITHDRAWAL PERIOD(S)

N/A

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children,
This veterinary medicinal product does not require any special storage conditions.
Do not use after the expiry date stated on the blister and carton. The expiry date refers to the last day of that month.
Unused halved tablets should be discarded. Do not remove tablets from the immediate packaging until required for use. Keep blister in outer carton.

12. SPECIAL WARNING(S)

Special precautions for use in animals
Do not use during pregnancy but may be used during lactation. Not intended for use in cats weighing less than 1 kg body weight.
After doses higher than 5 times the recommended dose, signs of intolerance such as vomiting have been observed. Parasitic resistance to a certain class of anthelmintics can occur after frequent and repeated use of an anthelmintic from this class. Fleas serve as intermediate hosts for one common type of tapeworm – Dipylidium caninum. Tapeworm infestation is certain to reoccur unless control of intermediate hosts such as fleas, mice, etc. is undertaken.
Special precautions to be taken by the person administering the veterinary medicinal product to animals
In case of accidental ingestion, seek medical advice and show the package leaflet to the physician. In the interests of good hygiene, persons administering the tablets directly to a cat or adding them to the cat's food should wash their hands afterwards.
For animal treatment only.
Other precautions
Echinococcosis represents a hazard for humans. As Echinococcosis is a notifiable disease to the World Organisation for Animal Health (OIE), specific guidelines on the treatment and follow-up, and on the safeguard of persons, need to be obtained from the relevant competent authority (e. g. experts or institutes of parasitology). If the cat

has visited areas where *Echinococcus* species. are prevalent, a veterinarian should be consulted.'

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

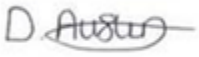
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2021

15. OTHER INFORMATION

AVM - GSL
Vm 40162/4007
2 tablets

Distributed by:
Johnson's Veterinary Products Ltd, Sutton Coldfield,West Midlands B75 7DF, UK
Tel: +44(0) 121 378 1684 info@johnsons-vet.com

Approved: 17/09/21