

JOHNSON'S VETERINARY PRODUCTS LTD

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT:

Johnson's Easy Tape-Wormer for Dogs.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Active ingredient: Dichlorophen 500mg per tablet.

3. PHARMACEUTICAL FORM:

Tablet.

4. PHARMACOLOGICAL PROPERTIES:

Dichlorophen is an anthelmintic used in the treatment of infection by tapeworms in dogs and cats. It is given orally in tablet form for the treatment of Taeniasis and Dipylidiasis infections, and the recommended dose for dogs is up to 300mg per kilogram bodyweight and for cats is between 100 – 200mg per kilogram bodyweight.

The mode of action is believed to act like salicylanilides by interfering with oxydative phosphorylation. Affected tapeworms are dislodged and disintegrate during their passage along the alimentary tract so they are not easily recognisable when passed 6-8 hours after dosing.

Occasional vomiting and diarrhoea may occur at above the normal recommended dose. There are no additional signs of toxicity at doses up to 1000mg per kg bodyweight, but at doses higher than these, nervous tremors, dullness, depression and diarrhoea can occur. Loss of weight and appetite may also occur. The minimum lethal dose is between 2000 and 3900mg per kg bodyweight.

ATC Vet Code QP52AG01.

5. CLINICAL PARTICULARS:

5.1 Target Species:

Dogs over 6 months of age.

5.2 Indications for Use:

Treatment for Tapeworms (Taenia and Dipylidium but not Echinococcus) in dogs over six months of age.

5.3 Contra-Indications:

Do not use on dogs under 6 months of age.
Do not use on puppies under 6 months of age.
Do not use on pregnant or nursing bitches.

5.4 Undesirable effects:

None.

5.5 Special Precautions for Use:

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.

5.6 Use during pregnancy and lactation:

Do not use on pregnant or nursing bitches.

5.7 Interaction with other medicaments and other forms of interaction:

None reported.

5.8 Posology and method of administration:

TAPEWORM TREATMENT FOR DOGS OVER 6 MONTHS OF AGE, WITH MINIMUM BODYWEIGHT OF 1.4kg (3lb)

1.4 to 2.0kg (3- 4lb)	½ tablet	15.1 to 18.0kg (34-39lb)	6 tablets
2.1 to 3.3kg (5- 7lb)	1 tablet	18.1 to 21.0kg (40-46lb)	7 tablets
3.4 to 4.9kg (8-10lb)	1-1½ tablets	21.1 to 24.0kg (47-53lb)	8 tablets
5.0 to 6.6kg (11-12lb)	2 tablets	24.1 to 27.0kg (54-59lb)	9 tablets
6.7 to 8.3kg (15-18lb)	2-2½ tablets	27.1 to 30.0kg (60-66lb)	10 tablets
8.4 to 10.0kg (19-22lb)	3 tablets	30.1 to 35.0kg (67-77lb)	11 tablets
10.0 to 12.5kg (23-27lb)	4 tablets	35.1 to 40.0kg (78-88lb)	12 tablets
12.6 to 15.0kg (28-33lb)	5 tablets		

For larger dogs, give 1 extra tablet for each additional 5kg (11lb) 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 preferably crushed and mixed with 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.

Occasional vomiting may occur with this drug as some animals vomit at will after administration of certain medicines, in which case 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. A repeat dose may sometimes be necessary, but if required should not be given until 2 to 3 weeks later. These tablets disintegrate the worms and no trace is usually seen after dosing.

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

Nervous signs, dullness and diarrhoea may occur. Treatment is symptomatic.

5.10 Special warnings for each target species:

It is advisable to consult a Veterinary Surgeon before treating pregnant animals and those with a history of epilepsy or disease of the kidneys. If signs of disease persist or appear, consult your Veterinary Surgeon.

5.11 Withdrawal periods:

Not applicable to companion animals.

5.12 Special precautions to be taken by the person administering the product to animals:

Wash hands after handling tablets.
In case of accidental ingestion, drink plenty of water and seek medical advice.

6. PHARMACEUTICAL PARTICULARS:

6.1 Incompatibilities (major):

6.2 Shelf-life:

3 years.

6.3 Special precautions for storage:

Do not store above 25°C. Store in a dry place.
Protect from light.

6.4 Nature and contents of container:

Cream mottled flat bevelled edge tablets with break-line on one side, packed in the following:

A) Container: Clear colourless regenerated cellulose/cellulose polyurethane/
polyethylene laminate strip-pack in fibreboard carton.

B) Container: Clear colourless polyvinylchloride/polyvinylidene chloride/aluminium
foil blister pack in fibreboard carton.

6.5 Special precautions for the disposal of unused product or waste materials, if any:

None.

7.0 Additional Information

Name and Address of Marketing Authorisation Holder:

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

MA No. Vm.01759/4054

Date of last approval/revision of SPC: 09.08.05

Date of last Renewal: 08.12.04

Conditions of supply: GSL

May be sold or supplied otherwise than by or under the supervision of a pharmacist as a medicinal product on a General Sales List.

<u>Issue No.</u>	<u>Date Issued:</u>	<u>Signed:</u>	<u>Position:</u>	<u>Reason for Issue:</u>
04	09.08.05		QP	Revised per MA Review – sections 2, 4, 5.3, 5.9, 5.12, 6.2, 6.3, 6.4, 6.5 and 7.