

JOHNSON'S VETERINARY PRODUCTS LTD

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT:

Johnson's Twin-Wormer for Dogs.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Active ingredient Dichlorophen 500mg per tablet, for the control of tapeworms (Taenia and Dipylidium but not Echinococcus)

Active ingredient Piperazine Phosphate 416mg per tablet for the control of ascarids (Toxascaris and Toxocara).

Also contains Amaranth (E123) as colourant.

3. PHARMACEUTICAL FORM:

Tablet.

4. PHARMACOLOGICAL PROPERTIES:

Dichlorophen BP:

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.

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.

Piperazine Phosphate BP:

Piperazine is used widely for the control of ascarid intestinal worms in dogs.

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.

ATC Vet Codes: QP52AH01 and QP52AG01.

5. CLINICAL PARTICULARS:

5.1 Target Species:

Dogs and Puppies (over 6 months of age).

5.2 Indications for Use:

Treatment for Roundworms and Tapeworms.

5.3 Contra-Indications:

Do not use on dogs or puppies under 6 months of age, or in animals less than 1.4 kg (3 lb).
Do not use Dichlorophen BP (Tapeworm treatment) on pregnant or nursing bitches, which should be treated for Roundworms only.

5.4 Undesirable effects:

Note: If animal is particularly sensitive, the following short term effects may occur: After giving the FAWN (Dichlorophen) tablet – occasional sickness or vomiting and slight transient loss of co-ordination.

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

5.6 Use during pregnancy and lactation:

It is advisable to consult a veterinary surgeon before treating pregnant animals.
Not suitable for Tapeworm treatment in pregnant or nursing bitches (see also 5.3)

5.7 Interaction with other medicaments and other forms of interaction:

None reported.

5.8 Posology and method of administration:

Treatment consists of 3 doses given at weekly intervals as shown below. Give the tablets 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.

1st dose: Give PINK tablets (roundworm treatment) as per table below, according to weight of animal.

2nd dose: 7 days after 1st dose, give FAWN tablets (tapeworm treatment) as table below.

3rd dose: 7 days after 2nd dose: repeat the 1st dose of PINK tablets as table below.

ACCURATE WEIGHING OF THE ANIMAL PRIOR TO DOSING IS ESSENTIAL

PINK TABLETS	No. of tablets	FAWN TABLETS	No. of tablets
Dog's Weight		Dog's Weight	
1.4 to 2.5kg (3- 5lb)	½ tablet	1.4 to 2.0kg (3- 4lb)	½ tablet
2.6 to 5.0kg (6-11lb)	1 tablet	2.1 to 3.3kg (5- 7lb)	1 tablet
5.1 to 7.5kg (12-16lb)	1½ tablets	3.4 to 4.9kg (8-10lb)	1½ tablets
7.6 to 10.0kg (17-22lb)	2 tablets	5.0 to 6.6kg (11-14lb)	2 tablets
10.1 to 15.0kg (23-33lb)	3 tablets	6.7 to 8.3kg (15-18lb)	2½ tablets
15.1 to 20.0kg (34-44lb)	4 tablets	8.4 to 10.0kg (19-22lb)	3 tablets
20.1 to 25.0kg (45-55lb)	5 tablets	10.1 to 12.5kg (23-27lb)	4 tablets
25.1 to 30.0kg (56-66lb)	6 tablets	12.6 to 15.0kg (28-33lb)	5 tablets
30.1 to 35.0kg (67-77lb)	7 tablets	15.1 to 18.0kg (34-39lb)	6 tablets
35.1 to 40.0kg (78-88lb)	8 tablets	18.1 to 21.0kg (40-46lb)	7 tablets
		21.1 to 24.0kg (47-53lb)	8 tablets
		24.1 to 27.0kg (54-59lb)	9 tablets
		27.1 to 30.0kg (60-66lb)	10 tablets
		30.1 to 35.0kg (67-77lb)	11 tablets
		35.1 to 40.0kg (78-88lb)	12 tablets

For larger dogs, give 1 extra tablet of Piperazine Phosphate BP 416mg (Pink tablet) for each additional 4kg (8.8lb) bodyweight.

For larger dogs, give 1 extra tablets of Dichlorophen BP 500mg (Fawn tablet) for each additional 5kg (11lb) bodyweight.

Do not administer more than 6 tablets as a single dose to large dogs. Remaining dose should be administered after 3 hours if no vomiting has occurred.

Occasional vomiting may occur after giving the Fawn tablets 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 of Fawn tablets may sometimes be necessary, but if required should not be given until 2 to 3 weeks later.

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

Dichlorophen: 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 kilo 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 kilo bodyweight. If signs of toxicity are present, consult a veterinary surgeon promptly, taking this packaging with you.

5.10 Special warnings for each target species:

None stated.

5.11 Withdrawal periods:

Not applicable.

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

Wash hands after handling tablets.

Accidental eye contact – rinse thoroughly with clean running water.

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:

Dichlorophen BP: Fawn mottled flat bevelled edge tablet with break-line one side

Piperazine Phosphate BP: Pink biconvex circular 9/16" tablet with ¼-break-line one side.

Standard Pack Size:

- i) Dichlorophen BP (Tapeworm treatment): 6 Fawn 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.
- Dosing device: Not applicable.
- ii) Piperazine Phosphate BP (Roundworm treatment): 8 Pink 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.
- Dosing device: Not applicable.

Large (Breeder) Pack Size:

- i) Dichlorophen BP (Tapeworm treatment): 12 Fawn 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.
- Dosing device: Not applicable.
- ii) Piperazine Phosphate BP (Roundworm treatment): 16 Pink 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.
- Dosing device: Not applicable.

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

None.

7. Final Information

Name and Address of Licence Holder/Marketing Company:

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

MA No. Vm.01759/4058

Date of last approval/revision of SPC: 28.09.05

Date of last Renewal: 24.03.05

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>
05	28.09.05		QP	Revised per VMD Renewal re Sections 2, 4, 5.3, 6.2, 6.5 and 7.