

JOHNSON'S VETERINARY PRODUCTS LTD

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT:

Johnson's Twin-Wormer for Cats.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Active ingredient Dichlorophen 250mg per tablet, for the control of tapeworms (*Taenia* and *Dipylidium* but not *Echinococcus*). Also contains Sepisperse (AP3018) as colourant.

Active ingredient Piperazine Phosphate 104mg per tablet for the control of ascarids (*Toxascaris* and *Toxocara*).

3. PHARMACEUTICAL FORM:

Film coated tablets.

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 oxidative 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 widely used for the control of ascarid intestinal worms in cats.

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) or on tapeworms.

ATC Vet Code: QP52AG01 and QP52AH01.

5. CLINICAL PARTICULARS:

5.1 Target Species:

Cats and Kittens over 6 months of age.

5.2 Indications for Use:

Treatment for Roundworms and Tapeworms.

5.3 Contra-Indications:

Do not use on cats or kittens under 6 months of age or less than 1.2 kg (2.75 lb) body weight.

Do not use Dichlorophen BP (Tapeworm treatment) on pregnant or nursing queens which should be treated for Roundworms only.

5.4 Undesirable effects:

Animals that are hypersensitive to dichlorophen may show signs of salivation, vomiting, anorexia and, rarely, hyperaesthesia, loss of co-ordination and weakness.

5.5 Special Precautions for Use:

Do not exceed the stated dose – accurate weighing of animal prior to dosing is essential.

Do not administer more than 2 or 3 tablets as a single dose – remainder of dose should be administered 4 hours later if no adverse reaction 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 queens (see also 5.2).

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 tablets immediately before a normal meal. Slip tablet on to back of tongue, hold mouth closed with head back and gently stroke neck until swallowed. The tablets may be smeared with butter for easier administration.

Give tablets according to weight of animal, as guide below.

1st dose: Give white tablets (roundworm treatment).

2nd dose: 7 days after 1st dose, give yellow tablets (tapeworm treatment).

3rd dose: 7 days after 2nd dose, repeat the 1st dose of white tablets.

ACCURATE WEIGHING OF THE ANIMAL PRIOR TO DOSING IS ESSENTIAL.

White tablets – 1 tablet per 1kg (2.2lb) bodyweight.

Yellow tablets – 1 tablet per 1.25kg (2.75lb) bodyweight.

The following table may be used as a guide:

White Tablets	Yellow Tablets
Cat's weight: <i>Up to 1.25kg (2.75lb): Consult Veterinary Surgeon</i>	
2.5kg (5lb) 2 tablets	2.0kg (4lb) 1 tablet
3.7kg (8lb) 3 tablets*	3.0kg (6lb) 2 tablets
5.0kg (11lb) 4 tablets*	4.2kg (9lb) 3 tablets *
6.3kg (14lb) 5 tablets*	5.5kg (12lb) 4 tablets *
7.5kg (17lb) 6 tablets*	6.9kg (15lb) 5 tablets *

* Do not administer more than 2 or 3 tablets as a single dose - remainder of dose should be administered 4 hours later if no adverse reaction has occurred. Keep animals under observation for several hours after dosing to ensure that tablets are ingested. Some animals vomit at will after administration of medicines, in which case do not repeat treatment if vomiting occurs shortly after dosing.

NOTE: If animal is particularly sensitive, the following short term effects may occur after giving the YELLOW tablets (Dichlorophen) – occasional sickness or vomiting, and slight transient loss of co-ordination, including weakness of limbs and unsteadiness, in which case consult a Veterinary Surgeon promptly, taking this packaging with you.

A repeat dose of yellow 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:

NOTE: If animal is particularly sensitive, the following short term effects may occur after giving the YELLOW tablets (Dichlorophen) – occasional sickness or vomiting, and slight transient loss of co-ordination, including weakness of limbs and unsteadiness, in which case consult a Veterinary Surgeon promptly, taking this packaging with you.

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 by humans – 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:

Pack Size:

Dichlorophen BP (Tapeworm treatment):

6 Yellow film-coated biconvex circular tablet with white biconvex circular core.

Piperazine Phosphate BP (Roundworm treatment):

12 White film-coated biconvex circular tablet with white deep biconvex circular core.

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.

7.0 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.01759/4059

Date of last approval/revision of SPC: 22.09.05

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>
04	22.09.05		QP	Revised: Sections 2, 4, 5.3, 5.4, 6.2, 6.5 and 7.0 amended per VMD Renewal, issued 12.09.05