JOHNSON'S VETERINARY PRODUCTS LTD

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF PRODUCT:

Johnson's Rid-Mite Insect Powder.

QUALITATIVE AND QUANTITATIVE COMPOSITION:

Active Ingredients:

Pyrethrum Powder 1.3% w/w (to give 0.1% w/w Pyrethrins)

8.17% w/w *
Piperonyl Butoxide

0.80% w/w

PHARMACEUTICAL FORM:

Cutaneous powder.

PHARMACOLOGICAL PROPERTIES:

Pyrethrins/Piperonyl Butoxide

Pyrethrum is a chrysanthemum derivative; the powdered, dried flower heads contain active principles mainly in the form of pyrethrins. Pyrethrins have insecticidal activity producing both knock-down and mortality in a range of insects, and low mammalian toxicity. Common names: dalmatian insect powder and Persian insect powder.

Piperonyl butoxide acts as a synergist when combined with pyrethrin and prolongs its action.

5. CLINICAL PARTICULARS:

5.1 Target Species:

Canaries, Budgerigars and Pigeons (but not those intended for human consumption).

5.2 <u>Indications for Use:</u>

Insecticidal powder to kill mites and lice on canaries, budgerigars and pigeons.

5.3 Contra-Indications:

Not to be used on pigeons intended for human consumption. If signs of disease persist or appear, consult a Veterinary Surgeon promptly.

5.4 Undesirable effects:

None

5.5 Special Precautions for Use:

For external use only.

5.6 <u>Use during pregnancy and lactation:</u>

Not contra-indicated.

^{*} Includes 5% stability overage.

5.7 Interaction with other medicaments and other forms of interaction:

None reported.

5.8 <u>Posology and method of administration:</u>

Directions for use - Cage birds (e.g. canaries and budgerigars) and Pigeons: Use early in the day to prevent birds inhaling powder while sleeping. Apply powder carefully and evenly over body, by hand if necessary, treating base of neck, tail, underwings and breast feathers, ensuring that powder reaches the skin. Avoid eyes. Apply sparingly, using 1-2g powder (2-3 gentle puffs) for a budgerigar or canary, and 3-5g powder (4-6 gentle puffs) for a pigeon. Repeat every 3-4 days if necessary until infestation is cleared. While treating birds, to help prevent reinfestation, a little powder may be dusted on to immediate surroundings where mites breed, eg. under sand trays, nesting materials, also cracks and crevices. Avoid contact with food and water. NOTE: Most effective way of treatment: one person holds the bird protecting its eyes with one hand, while second person parts feathers and applies powder.

Further information for breeders: As a periodic preventative and in cases of heavy infestation, treat birdrooms, cages, lofts, fittings and all cracks and crevices with a suitable long-acting liquid acaricide.

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

None stated

5.10 Special warnings for each target species:

None stated

5.11 Withdrawal periods:

Not applicable to companion animals.

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

Avoid inhaling powder. Avoid contact with eyes. Wash hands after use. Keep away from food and drink.

6. PHARMACEUTICAL PARTICULARS:

6.1 Incompatibilities (major):

6.2 Shelf-life:

30 months.

6.3 Special precautions for storage:

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

6.4 <u>Nature and contents of container:</u>

Pack Size: 55g and 110g

Container: White HDPE or polypropylene puffer bottle with one-hole LDPE plug

Closure: White polypropylene screw cap with spigot.

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

None.

Harmful to fish and crustaceans. Do not contaminate aquaria and fish bowls with the product.

7.0 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.01759/4039

Date of last revision of SPC: 23.10.03 Date Renewal issued: 08.09.03

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.

Issue No.	Date Issued:	Signed:	Position:	Reason for Issue:
05	26.11.03		QP	Revised – Inclusion of "Insect" in product name.