SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Veterinary Medicinal Product:

Johnson's Anti-Mite & Insect Spray, cutaneous spray, solution.

2. Qualitative and Quantitative Composition:

Pyrethrum Extract 25% 0.8% w/w Piperonyl Butoxide 1.0% w/w

For full list of excipients, see section 6.1.

3. Pharmaceutical form:

Cutaneous solution. A clear, yellow liquid.

4. <u>Clinical particulars:</u>

4.1 Target species:

Cage birds e.g. budgerigars and canaries, and pigeons.

4.2 <u>Indications for use, specifying the target species:</u>

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

4.3 Contra-Indications:

None stated.

4.4 Special warnings for each target species:

None stated.

4.5 Special precautions for use:

i) Special precautions for use in animals:

For external use only.

ii) Special precautions to be taken by the person administering the medicinal product to animals:

Highly flammable. Do not spray on a naked flame or any incandescent material.

No smoking when using this product.

Must be used in a well-ventilated area.

Do not breathe spray mist.

Avoid contact with eyes and skin.

In case of accidental eye contact, wash eyes with copious amounts of water. If irritation persists, seek medical advice

Persons who are hypersensitive (allergic) to pyrethrum extract should handle the product with care.

Treated animals should not be allowed to sleep or play with people, particularly children, until the animal is dry.

Wash hands after use.

Keep away from food, drink and animal feedingstuffs.

4.6 Adverse reactions (frequency and seriousness)

None reported.

4.7 <u>Use during pregnancy, lactation or lay:</u>

Not applicable.

4.8 Interaction with other medicinal products and other forms of interaction:

None reported.

4.9 Amounts to be administered and administration route:

Directions for use: Remove food and water before spraying. Avoid spraying from less than 24" (60cm) on perspex or plastic cage materials, as adverse reaction may result.

Cage Birds: (e.g. Canaries and Budgerigars): Spray directly at bird in the cage from about 24" (60cm). Avoid spraying into bird's eyes. Use sparingly, giving 2 or 3 one-second puffs only. For open cages, cover cage except front with a cloth and remove it a few minutes after spraying. For cages containing several birds, spray into cage from about 24" (60cm), in puffs of one-second, filling cage with light mist only. Repeat every 3-4 days until infestation is cleared. To help prevent reinfestation, also allow spray to fall on immediate surroundings where mites breed, e.g. cage surfaces, perch ends, cracks and crevices.

Pigeons: Treat birds singly inside loft. Spray each bird for 4-6 seconds only according to size. Spray lightly at rear of bird from about 15" (38cm), parting feathers. Avoid eyes. Repeat every 3-4 days until reinfestation is cleared. Use occasionally as a precaution, particularly after Racing or Showing. To help prevent reinfestation, also allow spray to fall on surroundings e.g. baskets, fittings, lofts. NOTE: most effective way of treatment: one person wearing rubber gloves holds bird, protecting its eyes with one hand, while second person parts feather and applies spray.

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

None stated.

4.11 Withdrawal periods:

Do not use on pigeons intended for human consumption.

5. <u>Pharmacological properties:</u>

Pharmacotherapeutic group: Ectoparaciticides, insecticides and repellents, Ectoparasiticides for topical use, incl. Pyrethrins and pyrethroids

ATC Vet code: QP53AC51

5.1 Pharmacodynamic properties:

Pyrethrins/Piperonyl Butoxide

The plant Pyrethrum is a chrysanthemate; 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.

5.2 <u>Pharmacokinetic particulars:</u>

No other information available.

6. Pharmaceutical particulars:

6.1 <u>List of excipients:</u>

Kerosene Odourless Isopropyl Alcohol Propane/Isobutane/Butane 30 Propellant

6.2 Incompatibilities:

None known.

6.3 Shelf-life:

Shelf life of the veterinary medicinal product as packaged for sale: 30 months.

6.4 Special precautions for storage:

Extremely flammable. Pressurised container: Protect from sunlight and do not expose to temperatures exceeding 50°C. Do not pierce or burn even after use. Keep away from sources of ignition - No smoking. Do not store above 25°C.

6.5 Nature and composition of immediate packaging:

Pack Size: 100ml (64g)

150ml (96g) 300ml (192g)

Container: Unlined tinplate aerosol can

Closure: Aerosol valve assembly capable to delivering 0.43g/sec of the product.

Not all pack sizes may be marketed.

6.6 <u>Special precautions for the disposal of unused veterinary medicinal products or waste</u> materials derived from the use of such products, if appropriate:

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

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

7. <u>Marketing Authorisation holder:</u>

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

8. Marketing Authorisation number(s):

Vm 01759/4037

9. Date of first Authorisation:

22.04.91

10. <u>Date of revision of the text:</u>

March 2010