Revised: 12 August 2008
App No: 00337/2008:

JOHNSON'S VETERINARY PRODUCTS LTD

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Veterinary Medicinal Product:

Johnson's Insecticidal Flea & Tick Drops 742mg, Cutaneous solution

2. Qualitative and Quantitative composition:

Permethrin 25:75 cis:trans pure 742mg per 1ml vial

For full list of excipients, see section 6.1

3. Pharmaceutical form:

Cutaneous solution.
Clear pale amber solution.

4. Clinical particulars:

4.1 Target Species:

Dogs over 8 weeks of age.

4.2 Indications for use, specifying the target species:

For the control of flea and tick infestations on dogs over 8 weeks of age, for a period of up to 4 weeks.

4.3 Contra-Indications:

Do not use on cats. This product is very poisonous to cats. It is important to ensure that cats do not groom the site of application on a dog which has been treated with this product. Seek veterinary advice immediately if this occurs.
Do not use on dogs less than 8 weeks of age.

4.4 Special warnings for each target species:

None.

4.5 Special precautions for use:

4.5 i) Special precautions for use in animals:

For external use only.
Do not massage into the dog's skin.
Do not apply to the dog's fur.

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

Avoid the drops coming into contact with your fingers.
Wash off any splashes immediately with plenty of clean water.
Avoid contact with eyes. In case of accidental eye contact, rinse with clean, fresh water. If eye irritation persists, seek medical advice.
Wash hands and exposed skin with soap and water after use.
Users making multiple applications, such as in kennels, should wear protective gloves (neoprene or nitrile, 0.3mm minimum thickness).
If you feel unwell as a result of handling this product, you should consult your Doctor.
Do not handle the area of application for 6 hours following treatment.

Treated animals should not be allowed to play or sleep with people, particularly children, for 8 hours immediately following treatment.
It is preferable to treat during the evening, when children are in bed.
Keep away from food and drink, including animal feeding stuffs.

4.5 iii) Other precautions:

Treated dogs should not be allowed to go swimming for 12 hours following treatment.

4.6 Adverse reactions (frequency and seriousness)

Potential transient localised irritation at the site of application in a small minority of dogs – should this occur, bathe the dog with shampoo and seek veterinary advice.

If your dog becomes unwell or shows any unusual signs of irritation, then you should consult your veterinary surgeon taking this pack, and if possible the vials, with you.

4.7 Use during pregnancy, lactation or lay:

Not for use on lactating bitches with puppies less than 2 weeks of age.

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

Do not administer any other flea control products to your dog during the 4 week period of protection.

4.9 Amounts to be administered and administration route:

For dogs weighing over 15kg (33lb) and over 8 weeks of age:

i) Only open one vial immediately prior to use, by holding upright and twisting the cap off, taking care not to squeeze the vial.
ii) Part the dog's coat to expose the skin between the shoulder blades, at the nape of the neck.
iii) Squeeze the entire contents of one vial on to the exposed skin.
iv) Open a second vial and apply by parting the dog's coat at the base of the tail, then squeeze the entire contents of the second vial on to the exposed skin.

Re-treat after 28 days if any re-infestation is apparent.
If the dog's coat is subsequently wetted, such as when shampooing, the 4 week period of protection may be reduced.
Not to be applied at intervals of less than 7 days.

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

Not applicable given pack size and tolerance in target species.

4.11 Withdrawal periods:

Not applicable.

5. Pharmacological properties:

ATC Vet code: QP53AC04

5.1 Pharmacodynamic properties:

Permethrin is a contact ectoparasiticide acting on the sodium channel. It attacks the peripheral nervous system and, in particular, the motor nerve terminals in the central nervous system. Broadly speaking, Permethrin causes knockdown in arthropods, inducing loss of co-ordination, spasms, tremors and ultimately death.

When topically administered, the solution will rapidly disperse across the surface of the skin by virtue of the carrier having a relatively low viscosity and a very low vapour pressure. This mobility of the solution, in combination with capillary action through the coat and across the skin, together with natural movement of the animal, ensures adequate dispersion. Given that a high flea mortality was achieved one day after topical administration of the solution, this indicates good coverage of the individual animals by the insecticide.

If Permethrin is orally administered to mammals it is rapidly metabolised and almost completely excreted via urine or faeces within a short period of time. The trans isomer is eliminated faster than the cis isomer, it being the more susceptible of the two to esterase attack. The major metabolic reactions are ester hydrolysis, ester cleavage, oxidation and conjugation. Permethrin does not have a tendency to accumulate in tissues. None of the metabolites of Permethrin show a higher acute toxicity than the base Permethrin. Given that this product is administered externally, absorption rates are considerably lower than when orally administered.

5.2 Pharmacokinetic particulars:

No other information available.

6. Pharmaceutical particulars:

6.1 List of excipients:

Diethylene glycol methyl ether.

6.2 Incompatibilities:

Do not administer other methods of on-animal flea control during treatment.

6.3 Shelf-life:

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

6.4 Special precautions for storage:

Do not store above 25ºC.
Protect from direct sunlight.
Do not freeze. Do not refrigerate.
Do not remove the vial from the pack until ready to use.

6.5 Nature and composition of immediate packaging:

White polypropylene single-use vial, 2ml capacity to give 1ml dose. Filled from base and heat sealed. Batch number and expiry date embossed onto base seal. Twist off cap to administer contents.
Final presentation to be two vials or six vials in a rigid plastic blister.

Secondary packaging: Rigid plastic blister
Solid board blister card.

Not all pack sizes may be marketed.

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

EXTREMELY DANGEROUS to fish and aquatic life. Do not contaminate ponds, waterways or ditches with the product or empty packaging.

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

7.0 Marketing Authorisation holder:

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

8. Marketing Authorisation number(s):

Vm01759/4068

9. Date of first Authorisation:

10.11.98

10. Date of revision of the text:

12.08.08