Revised: 20 May 2009
(Amended 6.1 and 6.5)
AN: 00336/2008

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Johnson's Flea & Tick Drops 742mg for Puppies & Small Dogs, Cutaneous solution

2. QUALITITIVE 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, 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 preference to treat during the evening when children are in bed.
Keep away from food and drink, including animal feeding stuffs.

4.5iii) 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 over 8 weeks of age weighing up to 15kg (33lb):

i) Only open the 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.

Re-treat after 28 days if any reinfestation 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 high flash point coupled with 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 (or 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 printed on vial. Twist off cap to administer contents.
Final presentation to be one vial or three 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. Treated dogs should not be allowed to swim for at least 12 hours following treatment.

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER(S)

Vm01759/4067

9. DATE OF FIRST AUTHORISATION

11.04.00

10. DATE OF REVISION OF THE TEXT

May 2009

Issue No	Date Issued	Signed	Position	Reason for Issue
06	07.10.08		QP	Revised: Sections 6.1 amended from brand name to generic name; section 6.5 - batch number and expiry date printed on vial, not embossed.