

1. Name of the Veterinary Medicinal Product

Wilko Dog Flea Powder, Cutaneous powder

2. Qualitative and Quantitative Composition

Active substance	% w/w
Pyrethrins (as Pyrethrum Powder 1.3%)	0.10
Piperonyl butoxide	0.80

For full list of excipients, see section 6.1.

3. Pharmaceutical form

Cutaneous powder

Free-flowing, white/grey powder.

4. Clinical Particulars

4.1 Target species

Dogs

Indications for use, specifying the target species

For the control of fleas on dogs.

4.3 Contra-indications

Do not use on puppies under 12 weeks of age.

Do not use on nursing females.

Do not use more than once a week.

No other insecticidal product should be used concurrently.

4.4 Special warnings for each target species

Remove fleas from young puppies and nursing females by careful use of a flea comb.

Fleas from pets often infest animal baskets, bedding and regular resting areas such as carpets and soft furnishings, which should be dusted also and vacuumed regularly.

If signs of disease persist or appear, consult a veterinary surgeon.

4.5 Special precautions for use

(i) Special precautions for use in animals

For external use only.

Avoid the eyes.

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

Avoid inhaling the powder. Use in a well ventilated area.

Wash hands and exposed skin after use.

Avoid contact with eyes. In case of accidental eye contact, rinse with clean, fresh water. If eye 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 powder has been brushed out.
Keep away from food and drink, including animal feeding stuffs.

4.6 Adverse reactions (frequency and seriousness)

None known

4.7 Use during pregnancy, lactation or lay

See section 4.3

4.8 Interaction with other medicinal products and other forms of interaction

Do not use any other insecticide within 7 days of treatment.

4.9 Amounts to be administered and administration route

Apply only when the coat is dry. Stand the animal on a sheet of paper or outdoors and comb or brush the coat the wrong way. Apply the powder close to the skin. Brush excess powder off the coat taking care to avoid the eyes and other sensitive areas. Brush out the coat after 30 minutes and do not allow the animal to groom itself until this has been done.

Repeat the treatment at weekly intervals if re-infestation is apparent.

Recommendations:

A small dog (e.g. terrier) will require 5 – 10 g powder, the pack containing sufficient for 8 – 16 applications. A medium size dog (e.g. collie) will require 10 – 15 g powder, the pack containing sufficient for 5 – 8 applications. A large dog (e.g. Alsatian) will require 15 – 20 g powder, the pack containing sufficient for 4 – 5 applications.

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

In case of an adverse reaction, consult a veterinary surgeon.
Treat symptomatically.

4.11 Withdrawal period(s)

Not applicable.

5. Pharmacological properties

Pharmacotherapeutic group: Ectoparasiticides for topical use, incl. insecticides

ATCvet code: QP53AC51

5.1 Pharmacodynamic properties

The powder contains the active ingredient Pyrethrins (from Pyrethrum powder 1.3% w/w) synergised by Piperonyl butoxide. Pyrethrum is rapidly toxic to many insects including fleas, this activity being enhanced by Piperonyl butoxide.

5.2 Pharmacokinetic particulars

The pyrethroids possess potent insecticidal activity with much lower mammalian toxicity.

6. Pharmaceutical particulars

6.1 List of excipients

Magnesium carbonate light
Silicon dioxide precipitated
Talc substitute (aluminium silicate combined with sericitic mica and chlorite)
Perfume

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

Store in a dry place.
Do not store above 25°C.
Keep away from food and drink, including animal feeding stuffs.

6.5 Nature and composition of immediate packaging

80 g of product contained within a polypropylene bottle fitted with a polypropylene lid with integral spout sealed by a 'flip-up' lid.

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

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

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

7. Marketing authorisation holder

Sinclair Animal and Household Care Ltd.
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DN21 2QB

8. Marketing authorisation number

Vm 16516/4011

9. Date of first authorisation/renewal of the authorisation

Date of first authorisation: 25 September 2001

10. Date of revision of the text

19 May 2008