AN: 00573/2014 Issued: April 2015

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Veterinary Medicinal Product

PetStar Soft Flea Collar, 180 mg/g, medicated collar

2. Qualititative and Quantitative Composition Active substance

Each gram contains:

Permethrin (40:60 cis:trans) 180 mg

1 collar contains:

Permethrin (40:60 cis:trans) 456 mg

Excipients

For the full list of excipients, see section 6.1

3. Pharmaceutical form

Medicated collar

Impregnated felt substrate (white) bonded to a nylon flock pile or reflective material closed by a slide grip buckle. The collar has an elasticated section and a bell.

4. Clinical Particulars

4.1 Target species

Cats

4.2 Indications for use, specifying the target species

For the control of fleas on cats for four months.

4.3 Contra-indications

Do not use on kittens under 12 weeks of age.

Do not use on pregnant or nursing females.

4.4 Special warnings for each target species

Remove fleas from young animals 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 treated with a suitable insecticide 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.

Do not allow animals to chew the collar.

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

Wash hands thoroughly with soap and water after handling the collar. Do not smoke, eat or drink while handling the collar.

AN: 00573/2014 Issued: April 2015

Do not allow children to play with the collar or to suck and chew on it. A pet wearing a flea collar should not sleep in bed with people, particularly children.

4.6 Adverse reactions (frequency and seriousness)

Occasionally a sensitive animal may experience localised skin irritation, in which case remove collar immediately.

4.7 Use during pregnancy, lactation or lay

Do not use on pregnant and nursing females.

4.8 Interaction with other medicinal products and other forms of interaction

Do not use any other insecticide on the cat while the collar is worn or within 7 days of removal. No other pesticide should be used in conjunction with this collar.

4.9 Amounts to be administered and administration route

One collar per animal to be fastened around the neck. Continuous protection will be provided for the 4 months that the collar is worn. Remove the collar from its protective blister and dispose of the empty blister in the dustbin. Fasten around the cat's neck, adjusting until a comfortable fit is achieved. If fitted on a growing cat, remember to loosen the collar as the cat grows. For a fully-grown cat, correct fitting will allow two fingers to be inserted between the collar and the neck. Cut off any excess length of collar extending beyond the buckle, wrap it and dispose of with the household refuse. Leave collar in place until the collar's effective life is exhausted.

4.10 Overdose (symptoms, emergency procedures, antidotes) if necessary In cases of adverse reaction, consult a veterinary surgeon.

4.11 Withdrawal period(s)

Not applicable

5. Pharmacological properties

Pharmacotherapeutic group: Ectoparasiticides for topical use, incl. insecticides ATCvet code: QP53AC04

5.1 Pharmacodynamic properties

The collar is impregnated with the active substance Permethrin (40:60 cis:trans) which is released over a four month period to provide control of the ectoparasite, the cat flea, which is the most common species of flea found on cats. Permethrin is a non-systemic insecticide with contact and stomach action. It acts on sodium channels of parasite nerve axons causing initial excitement then paralysis and death.

5.2 Pharmacokinetic particulars

Permethrin is a non-systemic acting insecticide active on the skin surface of the cat.

AN: 00573/2014 Issued: April 2015

6. Pharmaceutical particulars

6.1 List of excipients

Felt

6.2 Incompatibilities

None known.

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 25°C.

6.5 Nature and composition of immediate packaging

One collar (265 mm) contained in a PVC blister heat-sealed to a product card.

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 in accordance with local requirements.

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

7. Marketing authorisation holder

Sinclair Animal and Household Care Ltd. Ropery Road Gainsborough Lincolnshire DN21 2QB

8. Marketing authorisation number

Vm 16516/4036

9. Date of first authorisation

16 April 2015

10. Date of revision of the text

April 2015

Approved: 16 April 2015