

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the veterinary medicinal product

Armitage Pet Care Insecticidal Flea Shampoo & Conditioner

2. Qualitative and Quantitative Composition

Active Ingredient	% w/w
Pyrethrum Extract 25%	0.190
(equivalent to Pyrethrins	0.0475)
Piperonyl Butoxide (100%)	0.490
Other Ingredients	% w/w
Bronidox L	0.130
Carmoisine (E122)	0.0032

For full list of excipients, see section 6.1

3. Pharmaceutical form

Shampoo
Red, clear shampoo, pH 6.0

4. Clinical Particulars

4.1 Target species

Dogs over 12 weeks of age.

4.2 Indications for use, specifying the target species

For the control of fleas on dogs and puppies over 12 weeks of age.

4.3 Contra-indications

Do not use on cats
Do not use on puppies under 12 weeks of age.
Do not use on nursing females.

4.4 Special warnings for each target species

To help prevent re-infestation, dog's bedding, basket and regular resting areas such as carpets and soft furnishings should be treated with a suitable insecticide and vacuumed regularly. Remove fleas from young puppies and nursing females by careful use of a flea comb. 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 contact with the eyes.

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

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 especially children until the animal is dry.

Keep away from food and drink including animal feeding stuffs.

4.6 Adverse reactions (frequency and seriousness)

None reported.

4.7 Use during pregnancy, lactation or lay

Do not use on nursing females.

4.8 Interaction with other medicinal products and other forms of interaction

Other insecticides should not be used concurrently.

4.9 Amount(s) to be administered and administration route

Mix the recommended amount of shampoo with 300ml of lukewarm water. Wet the dog's coat thoroughly with warm water and apply half of the mixture.

Massage well into the coat, using fingertips around the head to avoid eyes, ears and mouth. Rinse and repeat with the remainder of the mixture working up to a good lather. Rinse well with lukewarm water and towel dry, then brush and comb thoroughly. Repeat in 7 days if necessary.

Recommendations:

Use 30ml of shampoo for a small dog (e.g. Terrier)

Use 50ml of shampoo for a medium dog (e.g. Collie).

Use 70ml of shampoo for a large dog (e.g. Alsatian).

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

Pharmacological properties

Pharmacotherapeutic group: Ectoparasiticides for topical use, incl. insecticides
ATCvet Code: QP53AC51

5.1 Pharmacodynamic properties

The shampoo is a liquid formulation containing the active ingredient Pyrethrins (from Pyrethrum Pale Extract (25%)). Pyrethrum is rapidly toxic to many insects, including fleas.

5.2 Pharmacokinetic particulars

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

5 Pharmaceutical particulars

6.1 List of excipients

Bronidox L (preservative)
Carmoisine (E122)
Water potable
Sodium lauryl ether sulphate
Coconut Diethanolamide
Sodium Chloride
Solan E50
Perfume
Citric acid monohydrate

6.2 Incompatibilities

None

6.3 Shelf life

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

6.4 Special precautions for storage

Close the bottle, store it upright. Protect from frost. Protect from direct sunlight.
Keep away from food and drink including animal feeding stuffs.

6.5 Nature and composition of immediate packaging

Container: food grade polymer PVC (clear) with HDPE screw cap.
Contents 250ml.
Labelled according to the conditions of the Marketing Authorisation.

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

Harmful to fish and crustaceans. Do not contaminate aquaria or 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.

6 Marketing authorisation holder

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

7 Marketing authorisation number

Vm 16516/4034

8 Date of the first authorisation

5 June 2006

9 Date of revision of the text
July 2017

Approved: 12 July 2017

A handwritten signature in black ink that reads "D. Austin" with a horizontal line extending to the right.