

SUMMARY OF THE PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Armitage Pet-Care Protect Flea Collar for Cats 15% w/w

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

<u>Active ingredient</u>	<u>% w/w</u>
Dimpylate	15

Each collar contains 2.1 g of dimpylate.

Excipients

The collars also contain the following pigments:

- heliogen K6911 HD	21 mg (blue strip)
- heliogen D8605 DD	14 mg (green strip)
- sicovit brown 75	105 mg (brown strip)
- sicopal brown K2595	21 mg (beige strip)
- paliogen K3911 HD	28 mg (red strip)
- paliogen K3911 HD	07 mg (pink strip)
- flash black 19976	42 mg (black strip)
- bayferrox 180 M	04.2 mg (grey strip)
- flash black 19976	01.12 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Collar.

Coloured collar of 14g – length 35 cm, available in blue, green, brown, beige, red, pink, black or grey.

4. CLINICAL PARTICULARS

4.1 Target species

Cats

4.2 Indications for use, specifying the target species

For the treatment and prevention of flea infestation in cats for up to 250 days.

4.3 Contra-indications

Do not use on kittens under 6 months of age

4.4 Special warnings for each target species

Remove collar from cat immediately should any signs of drowsiness, listlessness or respiratory difficulties develop soon after fixing of collar.

4.5 Special precautions for use

i. Special precautions for use in animals

Do not allow animals to chew the collar.
For external use only.

ii. Special precautions to be taken by the person administering the veterinary medicinal product to animals

Wash hands thoroughly after handling the collar.
Dimpylate is an organophosphorus compound. **Do not handle** if under medical advice not to work with ANTICHOLINESTERASES.
Do not allow children to play with collar.
Do not allow children to suck or chew the collar.
Do not sleep with pets wearing collars.
Do not smoke, eat or drink while handling the collar.
If you feel unwell after handling the collar, seek medical advice.

4.6 Adverse reactions (frequency and seriousness)

A slight irritation may appear on the neck due to the wearing of the collar. It is recommended to remove the collar from the animal until signs disappear.

4.7 Use during pregnancy, lactation or lay

Do not use in nursing females.
Remove fleas from young kittens and nursing females by careful use of a flea comb.

4.8 Interaction with other medicinal products and other forms of interaction

Do not use any other insecticide while the collar is being worn or within 7 days of removal.

4.9 Amounts to be administered and administration route

One collar per animal.
Remove collar from sachet or blister and fasten around the cat's neck, adjusting until a comfortable fit is achieved. In the fully-grown cat, correct fitting will allow one finger to be inserted between the collar and neck.
Any excess length of collar extending beyond the buckle should be cut off and disposed of in the household refuse. Leave in place until the collar effective life is exhausted. Activity remains extant against fleas for up to 250 days.

Fleas from pets often infest the animal's basket, bedding and regular resting areas such as carpets and soft furnishings which should be treated with a suitable insecticide and vacuumed regularly.

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

Dympylate is an organophosphorus compound and atropine sulphate is antidotal.

4.11 Withdrawal period

Not applicable

5. PHARMACOLOGICAL PROPERTIES

ATCvet code: QP53 AF03

Insecticidal collar for cats contains dympylate as a parasiticide

5.1 Pharmacodynamic properties

The product contains 15 % of dimpylate as insecticidal component. Dympylate is an organophosphorus compound which acts by inhibiting cholinesterases.

Dympylate, an organophosphorus parasiticide, is active against common fleas (*Ctenocephalides*).

Organophosphorus compounds act mainly by inhibiting insect enzymes such as cholinesterase responsible for degrading acetylcholine. As a result, cholinergic nerve transmission in the parasite is disrupted, inducing severe disorders such as spastic paralysis.

5.2 Pharmacokinetic properties

Due to the slow release of dympylate from the matrix of the collar, insecticidal activity remains for up to 250 days against fleas in cats.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Heliogen K6911 HD
Heliogen D8605 DD
Sicovit brown 75
Sicopal brown K2595
Paliogen K3911 HD
Flash black 19976
Bayferrox 180 M
Calcium carbonate
Calcium stearate
Epoxidised soya oil
Di isobutyl adipate
Calcium zinc complex LN 193R

Polyvinyl Chloride

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

6.4 Special precautions for storage

Store below 25 °C.
Protect from direct sunlight.
Keep away from direct heat.

6.5 Nature and composition of immediate packaging

Weight: 14 g - Length: 35 cm.
Collar available in blue, green, brown, beige, red, pink, black or grey.
The collars are packed individually in sachets or shells.
Sachet: thermo-sealed opaque white sachets composed of a four- layer film (kraft paper, polyethylene, aluminium and polyethylene).
Shell: transparent colourless shells of acrylonitrile/methyl acrylate/butadiene terpolymer, heat sealed.
Not all pack sizes may be marketed.

6.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

An unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.
EXTREMELY DANGEROUS to fish and aquatic life. Do not contaminate ponds, waterways or ditches with the collar or empty packaging.

7. MARKETING AUTHORISATION HOLDER

Virbac S.A.
1^{ère} avenue - 2065 m - L.I.D.
06516 Carros Cedex
France

8. MARKETING AUTHORISATION NUMBER

Vm 05653/4074

9. DATE OF FIRST AUTHORISATION

27 October 1999

10. DATE OF REVISION OF THE TEXT

August 2009