Revised: 22 July 2009
AN: 01905/2008

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Armitage Pet-Care Protect Flea and Tick Collar for Dogs 15% w/w

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient:	30 g collar	42 g collar
Dimpylate 15 % w/w ……...	4.5 g	6.3 g
Excipients:		
- for grey collar		
Red ferric oxide and ……	9 g	12.60 g
Flash black 19976 ……..	2.40 g	3.36 g
- for red collar		
Paliogen K3911 HD ……	60.0 g	84.0 g
- for blue collar		
Heliogen K6911 D ……...	45.0 g	63.0 g
- for green collar		
Heliogen NBK 8605 ……	30.0 g	42.0 g
- for black collar		
Flash black 19976 ……..	90.0 g	126.0 g

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Collar.
Coloured, supple plastic strip, provided with a buckle.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs over 12 weeks of age.

4.2 Indications for use, specifying the target species

Control of fleas and ticks on dogs.
Protection will be provided for up to 300 days against flea infestation and for up to 200 days against tick infestation.

4.3 Contraindications

Do not use on cats.

4.4 Special warnings for each target species

Do not allow the animals to chew the collar.
Fleas from pets often infest animals' basket, bedding and regular resting areas such as carpets and soft furnishings which should be treated with a suitable insecticide and vacuumed regularly. Remove fleas from young puppies and nursing bitches by careful use of a flea comb.

4.5 Special precautions for use

i. Special precautions for use in animals

Do not use on nursing bitches or puppies under 3 months of age.
REMOVE COLLAR FROM DOG IMMEDIATELY SHOULD ANY SIGNS OF DROWSINESS, LISTLESSNESS, HYPERSALIVATION, TREMOR OR RESPIRATORY DIFFICULTIES OCCUR SOON AFTER FIXING OF COLLAR.
For external use only.

ii. Special precautions for the person administering the veterinary medicinal product to animals

Wash hands thoroughly after handling the collar.
Dimpylate is an organosphosphorus compound: **do not handle** under medical advice not to work with ANTICHOLINESTERASES.
Do not allow children to play with the 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 following the use of this product, seek medical advice.

4.6 Adverse reactions (frequency and seriousness)

Occasional skin irritation and alopecia.
Remove collar and consult your veterinary surgeon if any sign of skin irritation or adverse reactions such as salivation or nervous signs occur.

4.7 Use during pregnancy, lactation or lay

Not for use on nursing or lactating bitches.

4.8 Interaction with other medicinal products and other forms of interaction

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

4.9 Amount(s) to be administered and administration route

Remove collar from blister and fasten collar around the dog's neck. When fitted to the growing dog, ensure the collar is loosened as the animal grows. In the fully-grown dog, correct fitting will allow two fingers to be inserted between the collar and the neck. Any excess length of collar extending beyond the buckles should be cut off and disposed of with the domestic refuse. The collar does not need to be removed when the animal is being bathed, as insecticidal activity remains unaffected by water. Leave in place until the collar effective life is exhausted.
Replace after 7 months if re-infestation is a risk.

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

Dimpylate is an organosphosphorus compound that causes acetylcholine accumulation in overdose. Atropine sulphate is antidotal. Overdose is characterised by abdominal pain, diarrhoea, salivation, tremors and pupil constriction.

4.11 Withdrawal period(s)

Not applicable

5. PHARMACOLOGICAL PROPERTIES

ATC Vet Code: QP53AF03

The collar contains 15% w/w of dimpylate. Dimpylate is an organosphosphorus insecticide which acts by inhibiting cholinesterases in insects.

5.1 Pharmacodynamic properties

Dimpylate, an organosphosphorus parasiticide, is active against common fleas (*Ctenocephalides*) and ticks. It acts mainly by inhibiting insect enzymes such as cholinesterases. This is achieved when dimpylate competes with acetylcholine, responsible for transmitting nerve impulses between cells, by binding to the esterase site of the cholinesterase molecules.
Acetylcholine, degraded at a lower pace, accumulates and induces disorders.
Because the metabolism of dimpylate in insects is very slow, irreversible poisoning is achieved

5.2 Pharmacokinetic particulars

The collar is a topical speciality. Due to the slow release of dimpylate from the matrix of the collar, parasiticidal activity remains extant for up to 300 days against fleas and for up to 200 days against ticks.
This collar is not for use in cats.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Red ferric oxide
Paliogen K3911 HD
Heliogen K6911 D
Heliogen NBK 8605
Flash black 19976
Calcium carbonate
Calcium stearate
Epoxidyzed soya bean oil
Di isobutyl adipate
Complex Calcium Zinc 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

Do not store above 25 °C. Keep away from direct heat and sunlight.

6.5 Nature and composition of immediate packaging

Supplied as either one 30g collar or one 42g collar in the following presentations;
Blister pack (shell): pocket and lid in acrylonitrile/methyl acrylate/butadiene co-polymer – thermo-sealed.
Paper/polyethylene/aluminium foil/polyethylene laminated heat sealed sachet.
One collar.
Not all collar sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product 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.
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.
1ère avenue - 2065 m - L.I.D.
06516 Carros Cedex
France

8. MARKETING AUTHORISATION NUMBER(S)

Vm 05653/4088.

9. DATE OF FIRST AUTHORISATION

Date: 31 October 2000

10. DATE OF REVISION OF THE TEXT

Date: July 2009