

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Johnson's Flea-Guard Waterproof Flea and Tick 15% w/w Collar for Dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Diazinon 15% w/w

Dyes

Black collar: flash black 19976 0.026 % w/w

Brown collar: flash black 19976 0.0087 % w/w

red ferric oxide 0.035 % w/w

Red collar: ariabel scarlet 0.5 % w/w

lithol rubine K4566 0.1 % w/w

Beige collar: flash beige 40232 0.3 % w/w

Green collar: tartrazine lake (E102) 0.28 % w/w

blue alphazurine lake 0.12 %w/w

titanium dioxide 0.1 % w/w

Blue collar: flash blue 47949 0.16 % w/w

Yellow collar: titanium dioxide (E171) 0.12 % w/w

quinoline yellow certolake 0.48 % w/w

flash yellow 47948 0.3 % w/w

White collar: titanium dioxide 0.15 % w/w

Pink collar: titanium dioxide 0.45 % w/w

lithol rubine K4566 0.001 % w/w

On the active strip, a reflecting band may be attached.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Collar:

24 g – 60 cm – coloured plastic strip provided with a buckle.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

For the control of fleas and ticks on dogs for up to 5 months.

4.3 Contraindications

Do not use on puppies under 12 weeks of age.

4.4 Special warnings for each target species

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

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. If you have several dogs, they must all be treated. Other animals in the same household should all be treated with an appropriate authorised product.

Ticks will detach from the host within 24-48 hours after infestation without having had a blood meal, as a rule. An attachment of single ticks after treatment cannot be excluded. For this reason, a transmission of infectious disease by ticks cannot be completely excluded if conditions are unfavourable.

4.5 Special precautions for use

- i) Special precautions for use in animals

Do not allow animals to chew the collar.

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

Do not remove collar from pack until ready to use.

DO NOT ALLOW CHILDREN TO PLAY WITH THE COLLAR.

Do not allow children to suck or chew the collar.

Do not smoke, eat or drink while handling collar.

Do not sleep with pets wearing collars.

Dimpylate/Diazinon is an organophosphorus compound: **DO NOT** handle if under medical advice not to work with **ANTICHOLINESTERASES.**

Avoid excessive handling of the collar.

Cut off any excess collar with scissors and dispose of safely.

If you feel unwell after handling the collar, seek medical advice.

Wash hands thoroughly after handling the collar.

4.6 Adverse reactions (frequency and seriousness)

Remove the collar immediately should any signs of skin irritation or adverse reaction occur.

Remove THE collar from dog immediately should any signs of drowsiness, listlessness, HYPERSALIVATION, TREMOR or respiratory difficulties develop soon after fixing of collar.

4.7 Use during pregnancy, lactation or lay

Not for use on nursing or lactating bitches.

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

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 Amounts to be administered and administration route

Insecticidal collar weighing 24 g and 60 cm in length, for use on dogs.
For external use only.

Remove the collar from blister and fasten 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, a correct fitting will allow two fingers to be inserted between the collar and the neck. Any excess length of collar extending beyond the buckle should be cut off with scissors and disposed of safely with the domestic refuse.

The collar does not need to be removed when the animal is being bathed as the insecticidal activity remains unaffected by water. Leave in place until the collar effective life is exhausted. Replace after 5 months if reinfestation with fleas or ticks is a risk.

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

Diazinon is an organophosphorus insecticide and atropine is antidotal. Remove the collar immediately if any signs of skin irritation or adverse reactions occur. Signs of overdosage include drowsiness, listlessness, hypersalivation, tremor or respiratory difficulties.

4.11 Withdrawal period

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Therapeutic group: ectoparasiticides for topical use, organophosphorus compounds.

ATCvet code: QP53AF03.

The collar contains diazinon as a parasiticide.

5.1 Pharmacodynamic properties

Diazinon, an organophosphorus parasiticide, is active against common fleas (*Ctenocephalides*) and ticks (*Rhipicephalus* or *Dermacentor*) of dogs. It acts mainly by inhibiting insect enzymes such as cholinesterases. This is achieved when diazinon competes with acetylcholine, responsible for nerve impulses, by binding to the esterase site of the cholinesterase molecules.

Acetylcholine, degraded at a lower pace, accumulates and induces disorders. Because the metabolism of diazinon in insects is very slow, irreversible poisoning is achieved.

5.2 Pharmacokinetic particulars

In mammals, cholinesterase activity similarly decreases. However, this is only transitory since enzyme synthesis is resumed and diazinon is degraded within a very-short period of time.

Diazinon being slowly released from the collar matrix, the product remains active for up to 5 months.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dyes

Black collar:	flash black 19976
Brown collar:	flash black 19976 red ferric oxide
Red collar:	ariabel scarlet lithol rubine K4566
Beige collar:	flash beige 40232
Green collar:	tartrazine lake (E102) blue alphazurine lake titanium dioxide
Blue collar:	flash blue 47949
Yellow collar:	titanium dioxide (E171) quinoline yellow certolake flash yellow 47948
White collar:	titanium dioxide
Pink collar:	titanium dioxide lithol rubine K4566 Dibutyl phthalate Soya-bean oil Calcium stearate Polyvinyl chloride

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 remove the collar from the pack until ready to use.

Do not store above 25 °C.

Protect from direct sunlight.

6.5 Nature and composition of immediate packaging

Blister pack of one 24-g impregnated-PVC collar: pocket and lid in acrylonitrile/methyl acrylate/butadiene co-polymer on backing card, heat sealed.

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

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
2065m – L.I.D.
06516 Carros Cedex
France

8. MARKETING AUTHORISATION NUMBER

Vm 05653/4100

9. DATE OF FIRST AUTHORISATION

Date: 23 January 2000

10. DATE OF REVISION OF THE TEXT

Date: March 2014

 24 March 2014