

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Beaphar Flea and Tick Collar for Dogs, 15% w/w.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

<u>Active substance</u>		<u>% w/w</u>	<u>mg/collar</u>
Dimpylate (as dimpylate stabilised)		15.0	3,600
<u>Excipients</u>		<u>% w/w</u>	<u>mg/collar</u>
Brown collar:	Ferric oxide red (E172)	0.08	19.2
	Charcoal, vegetable (E153)	0.02	4.8
Blue collar:	Coomassie Brilliant Blue G	0.012	2.8
	Copper Phthalocyanine	0.012	2.8
	OB (CAS No. 67210-66-6)	0.005	1.2
Red collar:	Rhodamine 6G	0.013	3.2
	Basic Violet 11	0.005	1.2
Yellow collar:	Solvent Yellow 135	0.013	3.2
Green collar:	Solvent Yellow 135	0.013	3.2
	Copper Phthalocyanine Green	0.010	2.4
Orange collar:	Disperse Yellow 11	0.010	2.4
	Rhodamine 6G	0.015	3.6
	Rhodamine B	0.005	1.2

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Collar
Coloured flea collar fitted with safety buckle

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

Treatment of dogs infested with fleas (*Ctenocephalides felis* and *C. canis*) and ticks (*Ixodes ricinus*).

4.3 Contra-indications

No other insecticide should be used with the collar or within 7 days of removal.
Do not allow the collar to come into contact with nursing females.
Do not use the collar on dogs younger than 12 weeks.

4.4 Special warnings for each target species

Remove collar if any sign of skin irritation occurs.
Check the collar is not too tight, to ensure against irritation.
Do not allow animals to chew the collar.
Remove collar from dog immediately should any signs of drowsiness, listlessness or respiratory difficulties develop soon after fixing the collar.

4.5 Special precautions for use

- (i) Special precautions for use in animals
For external use only.
Remove fleas from young puppies and nursing females by careful use of a flea comb.

- (ii) Special precautions to be taken by the person administering the 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.

- (iii) Other precautions
To help prevent reinfestation, animals' bedding and regular resting areas, including carpets and soft furnishings, should be treated with a suitable insecticide and vacuumed regularly.
After fitting the collar, do not allow dogs to swim in ponds or other small bodies of water. This will not adversely affect the activity of the collar but is potentially dangerous to aquatic life.

4.6 Adverse reactions (frequency and seriousness)

Typical adverse reactions to organophosphorus compounds are rare.

4.7 Use during pregnancy, lactation or lay

Do not allow contact with nursing females.

4.8 Interaction with other medicinal products and other forms of interaction

Do not combine with other organophosphorus compounds or medicines which are not compatible with organophosphorus compounds.

4.9 Amounts to be administered and administration route

One collar per animal to be fastened around the neck. Fasten the collar around the dog's neck, ensuring a comfortable fit; two fingers should fit easily under the collar. Loosen the collar as the dog grows bigger. Cut off excess collar extending beyond buckle and dispose of with the household refuse. Replace collar after 4 months if flea and tick re-infestation is a risk.

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

Symptoms: Tearing, salivation, muscle twitches, vomiting, loss of reflexes, coma, cyanosis.

Emergency procedure: Remove collar.

Antidote: Atropine.

4.11 Withdrawal period(s)

Not applicable

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ectoparasitocides for topical use, incl. insecticides
ATC Vet Code: QP53AF03

5.1 Pharmacodynamic properties

The collar is applied around the dog's neck. The collar constantly releases dimpylate over a four month period. Fleas and ticks on the skin of the animal come into contact with the dimpylate and are killed.

5.2 Pharmacokinetic particulars

Dimpylate is an organophosphorus compound with a non-systemic action.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Brown collar: Charcoal Vegetable (E153)

Ferric Oxide Red (E172)

Blue collar: Coomassie Brilliant Blue G

Copper Phthalocyanine
OB (CAS No. 67210-66-6)

Red collar: Rhodamine 6G
Basic Violet 11

Yellow collar: Solvent Yellow 135

Green collar: Solvent Yellow 135
Copper Phthalocyanine Green

Orange collar: Disperse Yellow 11
Rhodamine 6G
Rhodamine B

Polyvinyl chloride
Dibutyl Phthalate
Epoxidised Soya Bean Oil
Calcium Stearate

6.2 Incompatibilities

Morphine, theophylline, aminophylline, large amounts of intravenous fluids, phenothiazine drugs, pyrantelpalmoate.

6.3 Shelf life

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

6.4 Special precautions for storage

Protect from direct sunlight.

Do not store above 25°C.

Do not remove the collar from the pack until you are ready to fit it.

6.5 Nature and composition of immediate packaging

- (i) Clear, colourless high-density polyethylene blister, containing one PVC collar, heat sealed on varnished fibreboard/aluminium foil/fibreboard laminate backing card.
- (ii) Paper/aluminium foil/low density polyethylene sachet, containing one PVC collar, packed in a cardboard box.

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 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

Beaphar (UK) Ltd
Rook Tree Farm
Withersfield Road
Great Wratting
Suffolk
CB9 7HD

8. MARKETING AUTHORISATION NUMBER

Vm 05496/4001

9. DATE OF FIRST AUTHORISATION

15 January 1985

10. DATE OF REVISION OF THE TEXT

June 2018

Approved: 08 June 2018

