SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cat Flea Collar with Dimpylate 15% w/w

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance	% w/w	mg/collar
Dimpylate (as dimpylate stabilised)	15.0	2,100
Excipients	% w/w	mg/collar
Excipients Brown collar: Ferric oxide red (E172)	<u>% w/w</u> 0.08	mg/collar 11.2

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

Cats.

4.2 Indications for use, specifying the target species

Treatment of cats infested with fleas (Ctenocephalides felis).

4.3 Contraindications

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 cats younger than 6 months.

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 cat 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 kittens and nursing females by careful use of a flea comb.

ii. Special precautions for 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.

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.

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 Amount(s) to be administered and administration route

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

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

Symptoms:

Emergency procedure: Antidote: Tearing, salivation, muscle twitches, vomiting, loss of reflexes, coma, cyanosis. Remove collar. Atropine.

4.11 Withdrawal period

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ectoparasiticides for topical use, incl. insecticides.

ATC Vet Code: QP53AF03

5.1 Pharmacodynamic properties

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

5.2 Pharmacokinetic properties

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

5.3 Environmental properties

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Charcoal Vegetable (E153) Ferric Oxide Red (E172) Polyvinyl chloride Dibutyl phthalate Epoxidised Soya Bean Oil Calcium Stearate

6.2 Incompatibilities

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

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

Paper/aluminium foil/low density polyethylene sachet, containing one PVC collar.

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

Bob Martin (UK) Ltd. Wemberham Lane Yatton Somerset BS49 4BS U.K.

8. MARKETING AUTHORISATION NUMBER

Vm: 00715/4113

9. DATE OF FIRST AUTHORISATION

Date: 27 August 2010

10. DATE OF REVISION OF THE TEXT

Date: October 2013

Malton

Approved: 11/10/2013