## **SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bob Martin 15 % w/w Flea and Tick Collar for Dogs over 12 weeks old

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient: Dimpylate	15% w/w (3.6g per collar of 24g) (6.15g per collar of 41g)
Excipients: Flash black 19976 0.026% w/w	Black collar
Flash black 19976 0.0087% w/w and ferric oxide red (E172) 0.035% w/w	Brown collar
Ariabel scarlet 0.5% w/w or lithol rubine K4566 0.1% w/w	Red collar
Flash beige 40232 0.3% w/w	Beige collar
Tartrazine lake (E102) 0.28% w/w, blue alphazurine lake 0.12% w/w and titanium dioxide (E171) 0.1% w/w	Green collar
Flash blue 47949 0.16% w/w	Blue collar
Titanium dioxide (E171) 0.12% w/w and quinoline yellow aluminium lake (E104) 0.48% w/w or flash yellow 47948 0.3% w/w	Yellow collar
Titanium dioxide (E171) 0.15% w/w	White collar
Titanium dioxide (E171) 0.45% w/w and lithol rubine K4566 0.001% w/w	Pink collar

## 3. PHARMACEUTICAL FORM

Collar.

Coloured plastic strip provided with a buckle.

For a full list of excipients, see section 6.1

# 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

Do not allow animals to chew the collar.

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.

#### 4.5 Special precautions for use

i. Special precautions for use in animals

For external use only.

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

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

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 reactions occur.

Remove THE collar from dog immediately should any signs of drowsiness, listlessness, TREMOR, HYPERSALIVATION 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 dogs Insecticidal collar weighing 41 g and 65 cm in length, for large dogs.

Remove the collar from the sachet/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 and disposed of 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

Dimpylate is an organophosphorus insecticide and atropine is antidotal.

Remove the collar immediately if any signs of skin irritation or adverse reactions occur. Signs of over dosage include drowsiness, listlessness, tremor, hypersalivation or respiratory difficulties.

## 4.11 Withdrawal period

Not applicable

#### 5. PHARMACOLOGICAL PROPERTIES

ATC Vet Code: QP53AF03

The product contains diazinon as a parasiticide

#### 5.1 Pharmacodynamic properties

Dimpylate, an organophosphorus parasticide, 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 dimpylate 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 dimpylate 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 dimpylate is degraded within a very-short period of time. Dimpylate being slowly released from the collar matrix, the product remains active for up to 5 months.

#### 6. PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Flash black 19976

Ferric oxide red (E172)

Ariabel scarlet

Lithol rubine

Flash beige

Tartrazine lake (E102)

Blue alphazurine lake

Titanium dioxide (E171)

Flash blue

Quinoline yellow aluminium lake (E104)

Flash yellow

Polyvinyl Chloride

Calcium Stearate

Epoxidised Soya Bean Oil

Dibutyl Phthalate

## 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 24g or 41g collar: pocket and lid in acrylonitrile/methyl acrylate/butadiene co-polymer on backing card.

Sachet: paper/polyethylene/aluminium foil/polyethylene laminate.

Box containing one or two sachets of one 24g or 41g 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. 1 ère avenue – 2065m – L.I.D. 06516 Carros Cedex France

# 8. MARKETING AUTHORISATION NUMBER(S)

Vm 05653/4091

## 9. DATE OF FIRST AUTHORISATION

**Date:** 23/01/2000

## 10. DATE OF REVISION OF THE TEXT

Date: July 2009