

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Beaphar Flea & Tick Collar for Dogs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One collar of 65 cm length (26 g) contains:

Active substance:

Dimpylate (as stabilized diazinon at 92% diazinon) 3.9 g

Excipients:

Carbon black (E153) 0.004 g

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Collar

Black, PVC collar

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 ticks (*Ixodes ricinus*).

4.3 Contraindications

Do not use in case of hypersensitivity to the active substance, or to any of the excipients.

Do not use on sick and recovering dogs.

Do not use in dogs with known liver disorder.

Do not use in pregnant dogs.

4.4 Special warnings for each target species

When fitting, ensure that the collar is not too tight. Loosen the collar as the dog grows bigger.

4.5 Special precautions for use

Special precautions for use in animals

None known.

Special Precautions to be taken by the person administering the veterinary medicinal product to animals

Due to the potential risk of hypersensitivity developing in humans to dimpylate, unnecessary handling of this product should be avoided.

4.6 Adverse reactions (frequency and seriousness)

An intoxication typical for organophosphorus compounds occurs rarely. Rarely, local skin reaction at the site of collar application may occur. Such reactions may be associated with either skin sensitivity to some of the substances in the collar or an incorrectly fitted collar (too tight). If local skin reactions occur, remove the collar.

4.7 Use during pregnancy, lactation or lay

Use during pregnancy is not recommended.

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

4.9 Amounts to be administered and administration route

Dosage : One collar.

Administration: Fasten the collar around the dog's neck, ensuring a comfortable fit.

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

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

Emergency procedure: Remove the collar.

Antidote: Atropine. Sedation may be required to control excessive muscle activity.

4.11 Withdrawal Period(s)

Not applicable

5 PHARMACOLOGICAL or IMMUNOLOGICAL 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 properties

None given.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbon black (E153)
Polyvinyl chloride
Di-(2-ethylhexyl)phthalate
Di-isobutylphthalate
Calcium stearate
Zinc stearate
Epoxidised soya bean oil
Stearic acid
Calcium carbonate

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years

6.4 Special precautions for storage

Protect from sunlight.
Do not store above 25°C.
Store in closed package.

6.5 Nature and composition of immediate packaging

Sachet or blister, containing one PVC collar.
The sachet is a white paper, coated with aluminium and polyethylene.
The blister is an aluminium cardboard, built up in several layers, sealed with polyethylene foil.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Beaphar B.V.
Drostenkamp 3
PO Box 7
8100 AA Raalte
The Netherlands

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10455/002/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

23rd August, 2009

10 DATE OF REVISION OF THE TEXT

October 2016