

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Gullivers Flea & Tick Collar for dogs.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Per collar:

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.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs

4.2 Indications for use, specifying the target species

For the treatment of infestation of dogs with fleas (*Ctenocephalides felis*) and ticks (*Ixodes ricinus*).

4.3 Contraindications

Do not use in case of known hypersensitivity to the active ingredient.

Do not use on sick and recovering dogs.

Do not use in dogs with known liver disorder.

Do not use in pregnant bitches.

4.4 Special warnings for each target species

None known.

4.5 Special precautions for use

Special precautions for use in animals

None.

Special Precautions to be taken by the Person Administering the 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.

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 organophosphorous compounds or medicines which are not compatible with organophosphorous compounds.

4.9 Amounts to be administered and administration route

Dosage : 1 collar

Administration: put the collar around the neck of the dog

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

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

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: Ectoparasiticides for topical use.

ATCvet code: QP53AF03

5.1 Pharmacodynamic properties

The collar is applicated round the dog's neck. The collar is constantly excreting diazinon during a period of 4 months. Diazinon has a non-systemic action. Fleas and ticks on the skin of the animal come in touch with the diazinon and get killed.

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

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

6.5 Nature and composition of immediate packaging

A sachet or blister contains 1 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

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under National Waste Disposal Regulations.

7 MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.
Loughrea
Co. Galway
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10987/055/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2009

10 DATE OF REVISION OF THE TEXT