

ΠΑΡΑΡΤΗΜΑ 1: ΠΕΡΙΛΗΨΗ ΤΩΝ ΧΑΡΑΚΤΗΡΙΣΤΙΚΩΝ ΤΟΥ ΠΡΟΪΟΝΤΟΣ

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CAPUT SPRAY, pyrethrines and piperonyl butoxide, antiparasitic spray for topical use for dogs and cats.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One 180 g gas cylinder contains:

Active substances:

Extract of pyrethrum, decoloured and dewaxed 25% (equivalent to pyrethrines)	2.16 g 0.54 g)
Pyperonyl butoxide	4.32 g

Excipients and propellant q.s. to	180 g
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For a full list of the excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion in spray form for topical use.

4. CLINICAL PARTICULARS

4.1. Target species

Dogs and cats.

4.2. Indications use, specifying the target species

CAPUT SPRAY is indicated in the treatment of infestations of dogs and cats by fleas, lice and ticks.

4.3. Contraindications

Do not use in pups and kittens.

Do not use in diseased or convalescent animals, or those with skin lesions.

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

4.4. Special warnings for each target species

Avoid direct contact with the eyes, the inside of the ear and the mouth of the animal.

Consult a veterinary surgeon prior to applying to lactating or pregnant animals, or on pups.

Do not perform repeated treatments on cats.

4.5. Special precautions for use

Special precautions for use in animals

The product is toxic for bees.

Avoid contact between the product and the eyes and/or mouth of the treated animal.

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

Use protective gloves.

Avoid contact with eyes and mucosae and do not inhale.

After application of the product or in cases of skin contact, wash immediately with plenty of soap and water.

Do not eat or drink or smoke during use of the product. *Wash your hands after the use.*

In cases of accidental ingestion, immediately consult a doctor and show him/her the label.

During use, do not contaminate foods, drinks or containers intended to contain them. If the product is used in areas where subjects remain for long periods of time and in bedrooms, the room should be aired before using it again.

Do not spray in the air of the environment.

4.6. Adverse reactions (frequency and seriousness)

In rare cases, increase of salivation can be noticed.)

4.7. Use during pregnancy, lactation and egg lay

Safety of the medicinal product during pregnancy and lactation has not been stated.

Prior to use in pregnancy and lactation, consult a veterinary surgeon.

4.8. Interaction with other medicinal products and other forms of interaction

Do not use at the same time as other antiparasitics.

4.9. Posology and method of administration

Shake vigorously before use.

Apply CAPUT SPRAY raising the fur and rubbing so that the product comes into the greatest possible contact with the skin.

Dogs:

Vaporize for 2-3 seconds/kg b.w. (equivalent to 4.8-7.2 mg of pyrethrines and 38.4-57.6 mg of piperonyl butoxide/kg b.w.). infestation.

The treatment may be repeated after two weeks.

Cats:

Vaporize for 1-2 seconds/kg b.w. (equivalent to 2.4-4.8 mg of pyrethrines and 19.2-38.4 mg of piperonyl butoxide/kg b.w.). The treatment may be repeated after three weeks.

Do not spray on eyes, inner part of the ear and mouth.

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

Do not exceed the recommended doses. *Following an accidental oral intake or intake at dosages much greater than the recommended ones, transitory neurological signs, increased salivation or vomit may take place.*

4.11. Withdrawal periods

Not pertinent.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: ectoparasites for topical use.

ATCVet Code: QP53AC51

5.1. Pharmacodynamic particulars

CAPUT SPRAY is an external antiparasitic for dogs and cats based on pyrethrum extract containing natural pyrethrins possessing insecticidal activity and very low toxicity for mammals. The synergising action of piperonyl butoxide confers a high efficacy on these compounds against a wide range of arthropodal ectoparasites such as fleas, lice and ticks.

5.2. Pharmacokinetic particulars

The natural pyrethrins are poorly absorbed cutaneously, they are metabolised in the plasma and liver and are rapidly eliminated by the urinary and faecal routes.

6. PHARMACOKINETIC PARTICULARS

6.1. List of excipients

Polyglyceric esters of oleic acid.
Purified water
Perfume (Labiatae essential oils)
Butane/Isobutane/Propane

6.2. Incompatibilities

None known.

6.3. Shelf life

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

6.4. Special precautions for storage

- Store in a dry place, protected from light and sources of heat.
- Recipient under pressure, protect from sunlight and do not expose to a temperature exceeding 50°C.

- Do not pierce or burn even after use. Do not spray onto flames or onto hot surfaces.
- Extremely inflammable.
- Store the recipient in a well ventilated area.
- Store away from flames and sparks – Do not smoke.
- Avoid accumulation of electrostatic charge.

6.5. Nature and composition of immediate packaging

180 g one-piece gas cylinder closed by crimping of the valve, complete with spray button. The closure consists of a polypropylene cap.

6.6. Special precautions for the disposal of unused veterinary medicinal product or waste derived from the use of such products

All unused veterinary medicinal products or waste materials deriving from these medicinal products must be disposed of in compliance with the local regulations in force.

Do not contaminate water courses.

7. MARKETING AUTHORISATION HOLDER

FATRO S.p.A. - Via Emilia, 285 - Ozzano Emilia (BO), Italy.

8. MARKETING AUTHORISATION NUMBER

180g gas cylinder Marketing authorization number 103122026

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

23/5/1987-22/5/2007

10. DATE OF REVISION OF THE TEXT

18/1/2010

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not pertinent.

DISPENSING REGIM

Veterinary medicinal product not requiring a veterinary medical prescription.