CALMEDRAG® Oral tablets

ANXIOLYTIC.

Recommended as a treatment for the separation anxiety.
The treatment with Calmedrag® must be supported with conduct management therapy.

Technical Specification

SPECIES

Dogs.

DOSAGE FORM

Oral tablets.

THERAPEUTIC ACTION

Anxiolytic.

COMPOSITION

Each tablet contains:
Clomipramine Hydrochloride .....20 mg
(Equivalent to 17.9 mg of Clomipramine base)
Excipients q.s.p.....1 tablet.

PROPERTIES

Clomipramine Hydrochloride is a tricyclic anti-depressant that inhibits the reuptake of presynaptic serotonin and norepinephrine and with this produces anxiolytic, anti-compulsive, anti-aggressive and anti-depressant effects. As a result can be seen significant changes in the behavior of the dogs subjected to therapies with Clomipramine.

INDICATIONS

Recommended as a treatment for the separation anxiety.
The treatment with Calmedrag® must be supported with conduct management therapy.

ROUTE OD ADMINISTRATION AND DOSAGE

Oral route of administration.

Place the tablet as far as possible on the muzzle of the dog, keep the muzzle closed and stimulate the swallowing. It is recommended at the beginning of the therapy, to administer the product along with the food to reduce the possibility of side effects such as vomiting.

Active ingredient dose:

- 2 mg of Clomipramine Hydrochloride per 10 kg of body weight (2 mg/Kg) every 12 hours for 2-3 months.

Product dose:

- 1 tablet of CALMEDRAG® per each 10 Kg of body weight (1 tablet/10 Kg) every 12 hours for 2-3 months.
  It is advisable to suspend therapy gradually.

OVERDOSE: Clomipramine in general is a fairy safe medication and well tolerated by dogs. In this species the lethal dose is approximately between 50 and 100 mg/Kg per day, that is to say 12.5 to 25 times the recommended therapeutic dose.

Notwithstanding the foregoing, the overdose with tricyclic antidepressant can be life threatening (arrhythmia, convulsions, cardiac and respiratory arrest).

There is no known antidote for Clomipramine.

DRUG INTERACTIONS

- Due to the additive effects, Clomipramine must be administered with caution when used concomitantly with other anticholinergic agents or CNS depressants.
- Tricyclic antidepressants used with anti-thyroid agents may increase the potential risk of agranulocytosis.
- The cimetidine may inhibit the metabolism of the tricyclic antidepressants and increase the risk of toxicity.
- Its use in combination with sympathomimetic agents may increase the risk of cardiac effects (arrhythmia, hypertension, hyperpyrexia).
- Do not administer concomitantly with MAO inhibitors (Selegiline, Amitraz)

CONTRAINDICATIONS

- Do not administer to animals with known hypersensitivity to tricyclic agents.
- Do not administer to animals weighing less than 2.5 Kg.
- Do not administer to male breeding dogs.
- Do not administer to pregnant or nursing females.
- Do not administer to puppies less than 6 month old.
- Do not administer concomitantly with MAO inhibitors (Selegiline, Amitraz)

PRECAUTIONS

Manage with caution in dogs with a history of convulsions, gastrointestinal hypo-motility, urinary retention, heart rhythm abnormalities or increased intraocular pressure.

SPECIAL PRECAUTIONS FOR THE OPERATOR

- Wash hands thoroughly after handling and/or administering this product.
- Keep out of reach of children.
- The accidental ingestion should be considered dangerous.
- People with known sensitivity to Clomipramine must exercise caution handling this product.

WARNINGS

Keep out of reach of children.

ADVERSE EFFECTS

- The symptoms and adverse signs more frequently observed include nausea, vomiting and lethargy or transient drowsiness.
- The sedation typically occurs at the beginning of the therapy and is usually self-limiting, as soon as the dog becomes tolerant to it.
- The vomiting has been reported specially in dogs that have received the Clomipramine in an empty stomach, therefore it is recommended that administer it along with the food.
- There could be, although unlikely, anorexia, diarrhea, hyperactivity of liver enzymes and some cholinergic effects (for example, dry mouth).

OBSERVATIONS

Special precautions for the disposal of unused product or waste material:
Empty containers can be discarded as household waste, without any special precautions. Do not dispose of containers with product residues on the ground or water courses. For expired or unused products, contact the manufacturing laboratory.

CONSERVATION

Store in a cool and dry place, at room temperature between 15º y 30°C.

CONDITION OF SALE

Chile:Venta bajo receta médico veterinaria retenida
Uruguay: venta exclusiva bajo receta msp (receta verde)

PRESENTATION

Case with 30 tablets.

PREPARED BY

Laboratorio Drag Pharma Chile Invetec S.A.

RECORDS

Chile: Reg. SAG N° 2178
Uruguay: Reg. MGAP N° 2017A00466

COUNTRIES WHERE IT IS MARKETED

Importer in Uruguay by:

VIVAFIL S.A.
RIO NEGRO 1107 Montevideo - Uruguay, TEL 29001112
grupotecnovet@gmail.com
Technical Director: DMTV Diego Cuadrado.

Imported and distributed in Bolivia by:

ZOOFARMA
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Drag Pharma Lab is not responsible for the consequences of misuse of the products, and the use of this information without consulting a veterinarian