LEISGUARD 5 mg/ml oral suspension for dogs

QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance

Domperidone	5 mg

Excipients:

Methyl parahydroxybenzoate (E218)	1.80 mg
Propyl parahydroxybenzoate (E216)	0.20 mg
Quinoline yellow (E104)	0.20 mg

Pharmaceutical form

Oral suspension
Yellow suspension

CLINICAL PARTICULARS

Target species

Dogs

Indications for use, specifying the target species

To reduce the risk of developing an active infection and clinical disease in case of contact with *Leishmania infantum*, through the enhancement of the cell-mediated immune response.

The efficacy of the product has been demonstrated in dogs under multiple natural parasite exposure in zones with high infection pressure.

Control of clinical progression of canine leishmaniosis at early stages of the disease (dogs with low to moderate positive antibody levels and mild clinical signs such as peripheral lymphadenopathy or papular dermatitis).

Contraindications

Do not use whenever stimulation of gastric motility might be dangerous eg. In the presence of gastrointestinal haemorrhage, mechanical obstruction or perforation.
Do not use in animals with a known hypersensitivity to domperidone or any of the excipients.
Do not use in animals with prolactin-secreting pituitary tumor.
Domperidone is metabolized by the liver, therefore it should not be administered to animals with liver failure.

Special warnings for each target specie

In case of severe infections, adequate aetiological treatment should be established in order to lower the parasitic load prior to consider a treatment with this veterinary medicinal product. In all cases, and taking into account the highly variable evolution of the disease, close patient follow up is recommended in order to adapt the treatment to the clinical stage of the animal, as required.

Adverse reactions (frequency and seriousness)

At the dosages and duration recommended, this veterinary medicinal product is very well tolerated.

In clinical trials rare cases of galactorrhoea during treatment with Leisguard were reported. This is considered a consequence of the prolactine peaks induced by domperidone, which disappear after treatment discontinuation.

Use during pregnancy or lactation

Pregnancy - Reproduction studies were performed in laboratory animals with no evidence of drug related teratogenic or embryotoxic effects. Signs of maternal toxicity were not seen in laboratory animals at doses 20 times higher than the recommended dose. However, there are no adequate and well controlled studies in pregnant bitches; therefore this drug should be used during pregnancy only in accordance with the benefit/risk assessment by the responsible veterinarian.

Lactation - Administration of domperidone to lactating females of several species has been shown to induce an increase of milk production. Administration of Leisguard to lactating bitches is likely to induce the same effect.

Interaction with other medicinal products and other forms of interaction

Cabergoline is a dopamine agonist that inhibits prolactin release from the pituitary gland. Therefore, its effects are antagonistic to those of domperidone.
Do not administer with stomach antacids such as omeprazole, cimetidine, or antacids.
Domperidone should not be used with dopaminergic drugs such as dopamine or dobutamine.

Amounts to be administered and administration route

0.5 mg/kg/d, equivalent to 1 ml/10 kg of Leisguard, once daily, during 4 consecutive weeks.

Leisguard may be administered directly into the mouth or mixed with food. To ensure a correct dosage, body weight should be determined as accurately as possible
Shake well before use
There are several schedules of dosing:

A) for reducing the risk of developing an active infection and clinical disease in case of contact with *Leishmania infantum*,

In seronegative animals that have never showed any sign of *Leishmania spp.* infection, but live or travel to an endemic area, domperidone treatments should be programmed, taking into account the temporary prevalence of leishmaniosis vectors (*Phlebotomus spp.*) in the geographic area of the patient location or destination.

In high prevalence areas or in climates with a long infective season, one treatment every four months should be administered. In the Mediterranean area, it would be advised to treat in June, October and February.
In low prevalence areas, one treatment period at the beginning of the infective season and another treatment shortly after the end may suffice.

In all cases, the treatment strategy must be established by the attending veterinarian in accordance with the local incidence of the disease and temporary presence of the infective vectors.

B) For the Control of clinical progression of canine leishmaniosis at early stages of the disease

The treatment should be started immediately after diagnosis in order to help animals to self-limit the disease.

Treatment with Leisguard may be repeated as needed, in accordance with the clinical and serological follow up performed by the attending veterinarian.

Withdrawal period(s)

Not applicable.

PHARMACEUTICAL PARTICULARS

Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 30 months
Shelf-life after first opening the immediate packaging: 8 months

Special precautions for storage

Store in the original package.
Protect from light.

Nature and composition of immediate packaging

A 60 ml high-density polyethylene (HDPE) bottle closed with a low density polyethylene (LDPE) adapter and a HDPE child-proof screw-cap.
Carton box with one bottle and two syringes (LDPE barrel, polystyrene (PS) plunger and LDPE piston), one graduated up to 1,5 ml and the other graduated up to 5 ml.