DOMPERGO®

Composition: Suspension in a hydro-repellent vehicle.
Contains 6 g of Domperidone.
Excipient q.s.p. 100 ml.
Therapeutic Action: DOMPERGO® is a selective dopaminergic antagonist of D2 receptors.

(Domperidone)
Oral suspension for horses.
FOR VETERINARY USE.

INDICATIONS

It is indicated for:

A. Prophylaxis and treatment of intoxication by alkaloids derived from indole (or ergo alkaloids) (E+). Routine management of pastures associated with natural ryegrass or fescue exposes horses to a significant load of these types of mycotoxins, manufactured (biosynthesized) by symbiotic endophytes in the former case, produced by Neotyphodium lolii, and in fescue, by Neotyphodium Coenophialum or other parasitic fungi of spikes (Claviceps sp), in other grasses. The quantity and quality of alkaloid produced depend on environmental factors (drought, humidity, temperature, etc.), soil type, management practices (overgrazing, competition with other grasses, fertilization, planting season, etc.), and other variables specific to each animal in the population.
These indole alkaloid substances produce a number of clinical signs in different species. In mares, it affects the reproductive sphere in its various stages, presenting as agalactia, placental anomalies, prolonged deliveries, resorptions, lack of estrus, among other signs. In pregnant foals, numerous pathologies are also observed, including respiratory failure, osteoarticular alterations, decreased serum immunoglobulin, and perinatal death.
The signs in the foal (mainly osteoarticular) once established cannot be reversed; therefore, **DOMPERGO®** is mainly indicated as a prophylactic or therapeutic measure for mares exposed to this mycotoxin.

It can be summarized as follows:

1. DOMPERGO® should be administered 35 days before the expected foaling date. Treatment should be continued until the day of foaling, which is normally expected to occur on the estimated date or before it. If foaling does not occur within the predetermined period, after 7 days past that date, discontinue treatment. If, on the contrary, foaling occurs according to the prediction, colostrum and milk production tend to be normal or abundant. If necessary, treatment can be continued according to veterinary medical criteria.

2. DOMPERGO® is indicated in mares that start lactation with reduced or absent milk production. Treatment should be maintained according to the clinical picture and professional judgment, but generally does not need to be extended for more than 20 days.

3. DOMPERGO® is also administered in mares showing signs of low ovarian activity. In general, ovarian follicular growth and ovulation occur 15 to 17 days after starting treatment and should be assessed by palpation.
Once bred, the treatment may need to be maintained during the first 60 days to sustain the primary luteal body until progesterone production begins, originating from accessory luteal bodies, dependent on chorionic gonadotropin (days 35 to 50).
A complementary method of assistance is hormone analysis in blood (progesterone and estrogen), as synthetic progesterone treatment may be required.
In case the pregnant mare consumes grasses with toxins before administering DOMPERGO®, it does not normalize the presence of defects (especially osteoarticular) in the fetus.

DOMPERGO®

B. **DOMPERGO®** is indicated as an inducer of milk production, mainly in fillies with low milk production, whose cause is not the mentioned intoxication. The duration of treatment depends on the attending professional's judgment but generally does not need to extend beyond 20 days.
Domperidone's main clinical utility in other species and in humans has been its application as a normokinetic and antiemetic agent. Although this function does not have a direct application in horses, it has shown great potential for both clinical and experimental use in gastrointestinal surgery, as its proper administration prevents postoperative ileus. Its effects focus on the mechanical and functional restoration of gastro-duodenal evacuative peristaltic coordination.

Administration Route:
Oral. No prior preparation is required. It is presented in a direct-use dosing device.

Dosage:
The clinically established dose of domperidone for horses is 1.1 mg per kilogram of body weight, regardless of age or sex. It is advisable to administer it before feeding. **DOMPERGO®** has a potency of 60 mg/ml. Its adjustable dosing device contains 40 ml (1 ml = 55 kg body weight) and has a locking system every 10 ml (10 ml = 600 mg), with 10 ml being the dose for a 550 kg horse (routine dose). In total, each injector provides 4 routine doses (2400 mg = 2200 kg body weight). **DOMPERGO®** is administered every 24 hours.

Drug Interactions, Side Effects, and Contraindications:
DOMPERGO® has a high safety margin at the recommended dose and frequency. It should be noted that in states where high levels of bioavailability are required, it is advisable to administer up to 6 times the therapeutic dose to overcome the strong enterohepatic metabolism retention (first-pass metabolism). This has not been proven in horses.
Concomitant administration of anticholinergic drugs may counteract the action of domperidone. Atropine should not be administered together with **DOMPERGO®.**
The normokinetic action of the drug may influence the bioavailability of other drugs, but at usual doses, this effect is negligible. Although the metabolic pathway followed in horses has not been described, inhibitors of CYP3A4, a subgroup of the cytochrome P450, such as azole group antifungals (ketoconazole), macrolide antibiotics (erythromycin, clarithromycin, or azithromycin), protease inhibitor drugs (saquinavir, ritonavir, lopinavir, and others), and nefazodone, alter the bioavailability of domperidone, increasing its Cmax nearly threefold in experimental animals and humans.

Precautions:
Horses undergoing treatment can be kept on pastures and/or forages, although excessive fiber consumption should be avoided to prevent accelerated intestinal transit, as its kinetic activity is promoted by the medication. When administered at the recommended dose and frequency, it does not present any toxicity. **DOMPERGO®** should not be administered to humans or any animal species not expressly indicated.

Usage Restrictions:
Horses treated with **DOMPERGO®** should not be used for human consumption.
Intoxications: In case of accidental ingestion and if the patient is conscious, administer a large volume of water. If necessary, administer intravenous corticosteroids. Seek immediate medical attention and contact specialized toxicological assistance centers with the product container.

Information for Physicians:
Administer muscle relaxants and/or cholinergics.

Avelino Díaz 2533/35 (1406) - Bs.As - Argentina.
Tel/Fax: 4633-2794/5227
info@labfundacion.com.ar
www.laboratoriofundacion.com

Laboratorio FUNDACION
CIENCIA Y TECNOLOGÍA FARMACÉUTICA