TORZEMIN®

TORASEMIDE

VETERINARY USE

Oral diuretic for dogs.

Formula

Each tablet of TORZEMIN® 2.0 mg contains:
Torasemide ---------- 2,0 mg
Excipients q.s.p. ---------- 0,080 g
Each tablet of TORZEMIN® 4.0 mg contains:
Torasemide ---------- 4,0 mg
Excipients q.s.p. ---------- 0,160 g

TECHNICAL INFORMATION

Torasemide belongs to the pyridine-3-sulfonylurea class of loop diuretics, with action on the ascending limb of the loop of Henle. It interacts with the Na+-K+-2Cl-cotransporter system, located on the luminal membrane, blocking the active reabsorption of sodium and chloride and inhibiting the reabsorption of water in the collecting tubule, providing increased diuresis. Torasemide is rapidly absorbed by the oral route and peak plasma concentration is achieved within 1 hour. Its bioavailability ranges from 76% to 92% and it is highly bound to plasma proteins. The diuretic effect of torasemide is approximately the same under fed and fasting conditions. Therefore, it can be administered without regard to meals. Torasemide metabolism and elimination involve the processes of both hepatic biotransformation and renal excretion. Two metabolites, one dealkylated and one hydroxylated, have been identified in urine. The parent drug is metabolized by the hepatic cytochrome P450 families 3A4 and 2E1 and, to a lesser extent, by 2C9. However, the plasma concentration and urinary recovery of both active metabolites are low and, therefore, are not clinically significant in patients with normal kidney and liver function.

INDICATIONS

Torzemin® is an oral diuretic indicated for dogs.

DOSAGE AND HOW TO USE

Torzemin® should only be administered orally. The recommended dose is 0.2 mg/kg every 12 hours for 14 days, as shown below or at the discretion of the veterinarian:

Animal weight in kg	0.2 mg/kg dose every 12 hours
Torzemin® 2 mg	
2.5	¼ tablet
5.0	½ tablet
7.5	¾ tablet
10.0	1 tablet
15.0	1½ tablet

Animal weight in kg	0.2 mg/kg dose every 12 hours
Torzemin® 4 mg	
20.0	1 tablet
30.0	1½ tablet

According to the efficacy study carried out in dogs, Torzemin® was considered 100% effective when used at the 0.2 mg/kg dose every 12 hours for 14 days. If necessary, treatment can be extended up to Day 28, according to the results obtained in the safety study with the product.

CONTRAINDICATIONS

The product should not be administered to dogs with hypersensitivity to torasemide or the active ingredients of the sulfonylurea group.
Torzemin® is not indicated for pregnant or lactating female dogs, nor for those under 12 months of age, as studies have not been conducted in these groups.
Torzemin® is not recommended for dehydrated or hypovolemic and hypotensive dogs, nor for those with renal impairment and fluid and electrolyte imbalance.

DRUG INTERACTIONS

It is recommended to avoid the concomitant use of Torzemin® with potentially nephrotoxic drugs, such as non-steroidal anti-inflammatory drugs (NSAIDs), aminoglycosides, amphotericin B and other loop diuretics. Torasemide can decrease renal excretion of salicylates, leading to an increased risk of toxicity and sulfonamide hypersensitivity.
Torasemide can antagonize the action of oral antidiabetic agents.
In cases of concomitant administration of corticosteroids, potassium loss effects may be potentiated. No pharmacokinetic interactions have been reported following the coadministration of torasemide and digoxin; however, hypokalemia is likely to increase digoxin-induced arrhythmias.
The concomitant administration of torasemide with other drugs metabolized by the 3A4 (e.g., enalapril, buprenorphine, doxycycline, cyclosporine) and 2E1 (isoflurane, sevoflurane, theophylline) hepatic cytochrome P450 families can decrease drug clearance from the systemic circulation. The effects of angiotensin-converting enzyme inhibitors (ACEIs) can be enhanced when co-administered with torasemide. Blood pressure monitoring is recommended during treatment.

ADVERSE EFFECTS
Safety study conducted with Torzemin® at the recommended dose of 0.2 mg/kg every 12 hours for up to 28 consecutive days, showed that the product is safe. The adverse effects observed were mild and transient in nature, such as low appetite, increased fluid intake, emesis, soft stools, and low blood pressure, but without causing hypotension. Hematological test abnormalities, such as increased levels of hematocrit, red blood cell count and hemoglobin levels, hyperproteinemia, increased levels of albumin, serum creatinine, uremia, low potassium levels and hyponatremia have been observed. Increased urine production, resulting in more dilute urine (color, appearance, density) and increased pH. The increased urine output may cause dehydration.
Torzemin® increases fluid intake and urinary flow rate. It is essential to allow the patient free access to water. Torasemide can reversibly increase serum glucose concentration. Therefore, it is recommended to monitor blood glucose levels in diabetic patients.

PRECAUTIONS
The safety of Torzemin has not been investigated in pregnant or lactating female dogs, neither in dogs used for breeding, those under 1 year of age, or in animals weighing less than 2.5 kg.
Patients' renal function, complete blood count, serum electrolyte levels (sodium, potassium and chloride), and hydration status and blood pressure must be monitored throughout Torzemin® treatment. In patients with diabetes mellitus, blood glucose levels must be monitored throughout treatment, due to the potential increase in blood glucose levels.
Patients with pre-existing fluid and electrolyte imbalance must be previously treated, for these changes to be normalized before receiving torasemide and monitored throughout treatment. Torasemide must not be used concomitantly with other loop diuretics, to avoid potentiation of adverse effects, especially fluid and electrolyte disturbances and hypotension.
Blood pressure must be monitored when torasemide is used concomitantly with angiotensin-converting enzyme inhibitors.

POISONING AND OVERDOSE
In case of poisoning or overdose, seek the veterinarian's attention for evaluation and supportive treatment. In case of overdose, it is recommended to monitor blood pressure and the hydration status, check electrolyte levels, and run hematological and biochemical testing. Torzemin®, when administered in overdose (0.6 mg/kg and 1 mg/kg, every 12 hours) caused hypotension, dehydration, high hematocrit levels, increased red blood cell counts, hemoglobin levels, thrombocytopenia, hyperproteinemia, increased levels of albumin, serum creatinine, uremia, hypokalemia and hypochloremia. It can also cause prostration, apathy, anorexia, muscular tremors, drowsiness, lack of motor coordination, gastrointestinal disturbances (anorexia, emesis, stool consistency changes). In urine, it can cause changes, such as diluted urine (color, aspect, density) and pH alkalinization.

WARNINGS
Products for veterinary use must be kept out of the reach of children and pets. They should not be stored near foods, drinks and personal hygiene products. No safety studies have been conducted in dogs under 1 year of age, pregnant and lactating females, nor in animals weighing less than 2.5 kg. Dose adjustments should only be made under the indication and guidance of the pet's veterinarian.
People with known hypersensitivity to torasemide or sulfonamides should handle the product carefully. Due to the increased urinary frequency and dehydration potential, allow animals free access to water.

HOW SUPPLIED
Cartridge with 1 aluminum blister containing 10 bisected tablets of torasemide each (FREE SAMPLE).
Cartridge with 3 aluminum blisters containing each one 10 bisected tablets of torasemide.

STORAGE RECOMMENDATIONS
Keep it in a dry place, at room temperature (15°C to 30°C), away from direct sunlight and out of the reach of children and pets. In case of accidental ingestion, seek medical attention and take the product package with you.
Exposing the product to extreme conditions of heat, sunlight and humidity, disregarding the correct storage recommendations, may result in a decrease or loss of activity of the active ingredients.

Lot, manufacturing and expiration date: see packaging.

SALE UNDER THE VETERINARIAN'S PRESCRIPTION AND APPLICATION.

Product registered with the Ministry of Agriculture, Livestock and Food Supply under no. SP 001692-6 000005 on 6/21/2022.

Owner and manufacturer:
Biolab Sanus Farmacêutica Ltda.
Av. Francisco Samuel Lucchesi Filho, 1039 – Bragança Paulista – SP
CEP 12929-600 – CNPJ 49.475.833/0018-46 – SAC 0800 941 5566

Responsible technician: Daniela Ziolkowski, CRF-SP nº 29.486.

Expiry date: 24 months after the manufacturing date.

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