SUCRALVET ®

SUCRALFATE
ORAL GEL 240 mg/mL

SUCRALVET®

Registration Number Q-0666-032

FORMULA

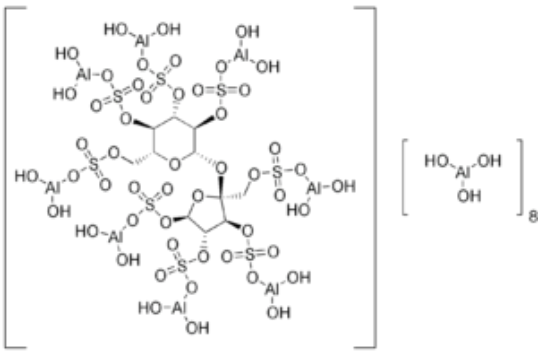
Each mL contains:
Sucralfate.....240.0 mg
Excipients c.b.p.....1 mL

THERAPEUTIC INDICATIONS

Sucralfate is an anti-ulcer drug with cytoprotective effect on the gastric mucosa used for the treatment of esophageal, gastric and duodenal ulcerations, as well as for the prevention of gastric erosions caused by medication.

It is chemically defined as a basic aluminum complex of sucrose sulfate (sulfated sucrose and aluminum hydroxide), presented as an amorphous powder, which is practically insoluble in alcohol or water.

Sucralfate is defined as a basic aluminum salt of sucrose sulfate (12H6O11[SO3-Al2(OH)5+] 8n H2O).



Sucralfate complex formed by sucrose octasulfate and polyaluminum hydroxide 12H6O11[SO3-Al2(OH)5+] 8n H2O.
It has a structure like heparin, but does not possess anticoagulant activity. It is also structurally related to sucrose, but is not utilized by the body as a sugar.
To exert its action, Sucralfate needs an acid pH (below 4) to be activated. The risks of overdose are minimal, since sucralfate is not absorbed.

PHARMACOLOGY

It is used in the treatment of oral, esophageal, gastric and duodenal ulcerations. Likewise, it has been used to prevent gastric erosions caused by medication. It acts forming a barrier creating a deposit on the gastric lesions covering the areas that have lost the mucosa and the superficial epithelium, this barrier stops the irritant action of the gastric juice. This substance can also act as a physical protective barrier against pepsin and bile acids on damaged or inflamed mucosal surfaces. At pH 3-4 sucralfate polymerizes to produce a very sticky, viscous yellowish gel that selectively binds to proteins in the ulcer crater, which remains adherent to the ulcerated epithelium for more than 6 hours. The sustained reaction with acid gradually consumes the Al2OH+5, until a certain amount of sucrose octasulfate halves are completely released to Al3+. Although the pH in the duodenum is well above 4, the gel retains its viscosity and emollient properties. Sucralfate has practically no acid neutralizing capacity, although it releases aluminum in the nearby injured areas, as if it were a local antacid. Besides being adherent to mucosal surfaces, locally it stimulates the formation of prostaglandins by the gastric mucosa, exerting a cytoprotective effect. The binding of sucralfate with the gastric mucosa lasts 6 hours and after 24 hours of a single dose there are no remains in the gastroduodenal mucosa. Food favors its disappearance in the normal mucosa, on the injured area it does not modify the sucralfate-protein interactions. In foals, sucralfate is protective against phenylbutazone-induced ulceration, but it is ineffective in curing subclinical

lesions in the non-glandular stomach mucosa.

Sucralfate decreases the absorption of several drugs such as quinolones, ketoconazole, lansoprazole, etc. All concomitant drugs should be taken two hours before sucralfate; sucralfate binds in the intestinal lumen to various drugs, decreasing their absorption, so it is advisable to separate their intake by at least one hour Anti-secretory drugs can alter the absorption of other drugs due to the increase they produce in the intraluminal pH. By this mechanism they can also decrease the absorption of vitamin B-12 from the diet, iron and calcium.

PHARMACOKINETICS
When the pH is below 4, sucralfate dissociates in gastric acid to sucrose octasulfate and aluminum hydroxide. While aluminum hydroxide acts as an antacid, sucrose octasulfate polymerizes to a viscous, sticky substance in an acidic environment and creates a protective effect by binding to the ulcerated mucosa. This prevents backscattering of hydrogen ions, inactivates pepsin, and absorbs bile acid, maintains mucosal blood flow by stimulating local prostaglandins, which, in turn, stimulates bicarbonate production and mucus secretion, It is an orally administered drug, with minimal oral absorption (between 0.5 and 2.2% of the ingested dose), which is excreted in the urine after 4 hours.

CONTRAINDICATIONS:
The only complication of its administration in felines is the poor tolerance of most patients to the suspension form, and its continued use usually leads to constipation, which is not very serious but requires discontinuation of treatment.

Use in: Domestic canines, felines and Equines.

Dosage:
Domestic canines: 20 to 40 mg/ kg body weight. In low dose: 1 mL for each 12 kg, In high dose: 1 mL for each 6 kg.
Felines: 20 mg/kg body weight, 1 mL/5 kg.
Equines: 10 to 20 mg/ kg body weight. In low dose: 1 mL for each 24 kg, In high dose: 1 mL for each 12 kg 3.

Dosage and duration of treatment will be according to the clinical case and Veterinarian Doctor's criteria.

ROUTE OF ADMINISTRATION:
Oral

GENERAL PRECAUTIONS:
It should be administered on an empty stomach, since it may delay or partially cancel the absorption of other drugs. Sucralfate is not absorbed after oral administration, so it lacks systemic effects. Aluminum toxicity is unlikely, except in patients with advanced chronic renal insufficiency.

WARNINGS

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	SUCRALVET ® **SUCRALFATE** **ORAL GEL 240 mg/mL**

Due to its local effect and poor systemic absorption, with infrequent and minor adverse effects that remit quickly without the need to suspend treatment. The most frequent is constipation, and to a lesser extent, non-specific symptoms such as dry mouth, nausea, headache, dyspepsia, dizziness, etc.

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COMMERCIAL PRESENTATION:
Box with dosing syringe with 15 and 30 mL.

STORAGE RECOMMENDATIONS:
Store in a cool dry place at not more than 30 °C and protected from direct sunlight.

PROTECTIVE LEGENDS:
Keep tightly closed.
Keep out of the reach of children, domestic animals or handicapped persons.
Do not administer this product in equines for human consumption.
Product for exclusive use in Veterinary Medicine.

ITS SALE REQUIRES MEDICAL PRESCRIPTION
CONSULT YOUR VETERINARIAN

Exclusive literature for veterinarians.
Responsible for content: Technical Department.
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