Sodium Tartrate

Disodium L-Tartrate; E335 (sodium tartrate or monosodium tartrate); Sodu winian; Tartrato de sodio.

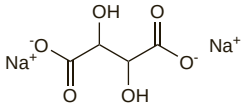
Виннокислый Натрий

$C_2H_4O_2(CO_2Na)_2,2H_2O$ = 230.1.

CAS — 868-18-8 (anhydrous sodium tartrate); 6106-24-7 (sodium tartrate dihydrate).

ATC — A06AD21.

ATC Vet — QA06AD21.



(anhydrous sodium tartrate)

Pharmacopoeias. In *USNF.*

USNF 26 (Sodium Tartrate). Transparent, colourless, odourless crystals. Freely soluble in water; insoluble in alcohol. pH of a 10% solution in water is between 7 and 9. Store in airtight containers.

Profile

Sodium tartrate has been used as an osmotic laxative. It is used as a food additive.

For the general properties of sodium salts, see p.1686.

Preparations

Proprietary Preparations (details are given in Part 3)
Canad.: Limonade Asepta.

Multi-ingredient: ***Arg.:*** Oral-B Enjuague Bucal Amosan†.

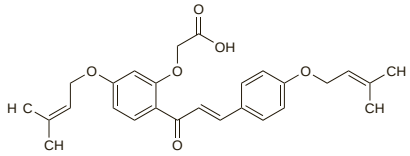
Sofalcone *(pINN)*

Sofalcona; Sofalconum; SU-88. {5-[(3-Methyl-2-butenyl)oxy]-2-{*p*-[(3-methyl-2-butenyl)oxy]cinnamoyl}phenoxy}acetic acid.

Софалькон

$C_{27}H_{30}O_6$ = 450.5.

CAS — 64506-49-6.



Profile

Sofalcone is reported to possess cytoprotective properties and is used in the treatment of gastritis and peptic ulcer disease (p.1702). An oral dose of 100 mg is given 3 times daily.

◊ References.

1. Isomoto H, *et al.* Sofalcone, a mucoprotective agent, increases the cure rate of Helicobacter pylori infection when combined with rabeprazole, amoxicillin and clarithromycin. *World J Gastroenterol* 2005; **11:** 1629–33.

Preparations

Proprietary Preparations (details are given in Part 3)
Jpn: Solon.

Sterculia

E416; Goma esterculia; Indian Tragacanth; Karaya; Karaya Gum; Sterculia Gum; Sterkülia.

Камедь Карайи; Стеркулия Жгучая (*Sterculia urens*)

CAS — 9000-36-6.

ATC — A06AC03.

ATC Vet — QA06AC03.

Pharmacopoeias. In *Br.* and *Fr.*

BP 2008 (Sterculia). The gum obtained from *Sterculia urens* and other species of *Sterculia*. Irregular or vermiform pieces, greyish-white with a brown or pink tinge, with an odour resembling that of acetic acid. It contains not less than 14.0% of volatile acid (or not less than 10.0% if supplied in powdered form), calculated as acetic acid. Sparingly soluble in water, but swells into a homogeneous, adhesive, gelatinous mass; practically insoluble in alcohol. Store at a temperature not exceeding 25°.

Adverse Effects and Precautions

As for Ispaghula, p.1737. There is a risk of intestinal or oesophageal obstruction and faecal impaction, especially if such compounds are swallowed dry. Therefore they should always be taken with sufficient fluid and should not be taken immediately before going to bed. They should be avoided by patients who have difficulty swallowing.

Uses and Administration

Sterculia is used similarly to ispaghula (p.1737) as a bulk laxative and for adjusting faecal consistency. It has also been used as an aid to appetite control in the management of obesity (p.2149) but there is little evidence of efficacy. It is usually taken in the form of granules containing sterculia 62%; the dose is 1 to 2 sachets or 1 to 2 heaped 5 mL spoonfuls orally once or twice daily after meals. (For a dose in children see below.) The granules are washed down without chewing with plenty of water. They may also be taken sprinkled onto soft foods such as yogurt.

Sterculia is used topically, as a paste or powder, for skin protection and sealing in the fitting of ileostomy and colostomy appliances. It has also been used in dental fixative powders, and as an emulsifier and stabiliser in foods.

Administration in children. In the UK, the recommended oral dose of granules, containing sterculia 62%, for constipation in children aged 6 to 12 years is ⁄ to 1 sachet, or ⁄ to one 5 mL spoonful, once or twice daily after meals. Children over 12 years may be dosed as for adults, see Uses and Administration, above. The granules are washed down without chewing with plenty of water. They may also be taken sprinkled onto soft foods such as yogurt.

Preparations

BP 2008: Sterculia Granules.

Proprietary Preparations (details are given in Part 3)
Austral.: Normafibe; ***Belg.:*** Normacol†; ***Braz.:*** Corega; ***Canad.:*** Normacol; ***Fr.:*** Inolaxine†; Normacol; ***Ger.:*** Decorpa†; Granamon†; ***Hong Kong:*** Normacol; ***Irl.:*** Normacol; ***Ital.:*** Normacol; ***Malaysia:*** Normacol†; ***Neth.:*** Normacol; ***NZ:*** Normacol; ***S.Afr.:*** Normacol; ***Singapore:*** Normacol; ***Swed.:*** Inolaxol; ***Switz.:*** Colosan mite; Inolaxine; Normacol; ***Thai.:*** Normacol†; ***UK:*** Normacol.

Multi-ingredient: ***Austral.:*** Alvercol†; Granocol†; Normacol Plus; ***Belg.:*** Normacol Antispasmodique†; Normacol Plus†; ***Fr.:*** Kaologeais; Karayal; Normacol a la Bourdaine†; Poly-Karaya; ***Hong Kong:*** Normacol Plus; ***India:*** Kanormal; ***Irl.:*** Normacol Plus; ***NZ:*** Granocol; Normacol Plus; ***Port.:*** Normacol Plus; ***S.Afr.:*** Alvercol†; Normacol Plus; ***Singapore:*** Normacol Plus; ***Spain:*** Normacol Forte; ***Switz.:*** Colosan plus; Normacol avec bourdaine nouvelle formule†; ***UK:*** Normacol Plus; Spasmonal Fibre†; ***Venez.:*** Polifix†.

Sucralfate *(BAN, USAN, rINN)*

Sucralfato; Sucralfatum; Sukralfaatti; Sükralfat; Sukralfat. Sucrose hydrogen sulphate basic aluminium salt; Sucrose octakis(hydrogen sulphate) aluminium complex; β-D-Fructofuranosyl-α-D-glucopyranoside octakis (hydrogen sulphate) aluminium complex.

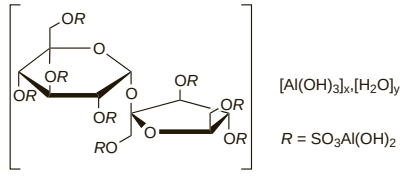
Сукральфат

$C_{12}H_mAl_{16}O_nS_8$.

CAS — 54182-58-0.

ATC — A02BX02.

ATC Vet — QA02BX02.



Pharmacopoeias. In *Chin., Jpn,* and *US.*

USP 31 (Sucralfate). The hydrous basic aluminium salt of sucrose octasulfate. Store in airtight containers.

Adverse Effects and Precautions

Constipation is the most frequently reported adverse effect of sucralfate although diarrhoea, nausea, vomiting, flatulence, or gastric discomfort may also occur. Other adverse effects include dry mouth, dizziness, drowsiness, headache, vertigo, back pain, and skin rashes. Hypersensitivity reactions such as pruritus, oedema, urticaria, respiratory difficulty, rhinitis, laryngospasm, and facial swelling have been reported.

Great caution is needed in patients with renal impairment (below) as absorption and accumulation of aluminium may cause adverse effects.

Bezoar formation. As of March 1999, the UK CSM was aware of 7 reports worldwide of bezoar formation associated with sucralfate use in intensive care patients.[1] It advised caution in the use of sucralfate in seriously ill patients because of the risks of bezoar formation and intestinal obstruction.[1] Patients with delayed gastric emptying or receiving concomitant enteral feeds may be at increased risk. A report by the French Pharmacovigilance System at about the same time made similar recommendations but also contra-indicated the use of sucralfate in premature and immature neonates.[2]

1. Committee on Safety of Medicines/Medicines Control Agency. Bezoar formation with sulcralfate [sic] (Antepsin). *Current Problems* 1999; **25:** 6. Also available at: http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&dDocName=CON2023235&RevisionSelectionMethod=LatestReleased (accessed 07/11/06)
2. Guy C, Ollagnier M. Sucralfate et bézoard: bilan de l'enquête officielle de pharmacovigilance et revue de la littérature. *Therapie* 1999; **54:** 55–8.

Renal impairment. Sucralfate under acid conditions can release aluminium ions that may be absorbed systemically. Significant increases in the urinary excretion of aluminium have been seen in healthy subjects given sucralfate 4 g daily,[1,2] reflecting gastrointestinal absorption of aluminium; aluminium concentrations in serum and urine were significantly higher in patients with chronic renal impairment than in subjects with normal renal function,[3] and similar serum increases have been seen in children with acute renal failure.[4] Aluminium toxicity in patients with normal renal function receiving sucralfate would not be expected, but seizures, muscle weakness, bone pain,[1] and severe aluminium encephalopathy[5] have been reported in patients with end-stage renal disease requiring dialysis. Sucralfate should be used with caution in patients with renal impairment, especially if other aluminium-containing agents are also taken, and such patients should be monitored for signs of aluminium toxicity.[4,6]

1. Robertson JA, *et al.* Sucralfate, intestinal aluminium absorption, and aluminium toxicity in a patient on dialysis. *Ann Intern Med* 1989; **111:** 179–81.
2. Allain P, *et al.* Plasma and urine aluminium concentrations in healthy subjects after administration of sucralfate. *Br J Clin Pharmacol* 1990; **29:** 391–5.
3. Burgess E, *et al.* Aluminum absorption and excretion following sucralfate therapy in chronic renal insufficiency. *Am J Med* 1992; **92:** 471–5.
4. Thorburn K, *et al.* Aluminum accumulation in critically ill children on sucralfate therapy. *Pediatr Crit Care Med* 2001; **2:** 247–9.
5. Withers DJ, *et al.* Encephalopathy in patient taking aluminium-containing agents, including sucralfate. *Lancet* 1989; **ii:** 674.
6. Hemstreet BA. Use of sucralfate in renal failure. *Ann Pharmacother* 2001; **35:** 360–4.

Interactions

Sucralfate may interfere with the absorption of other drugs and it has been suggested that there should be an interval of 2 hours between giving sucralfate and other non-antacid medication. Some of the drugs reported to be affected by sucralfate include cimetidine, ranitidine, digoxin, fluoroquinolone antibacterials, ketoconazole, levothyroxine, phenytoin, tetracycline, quinidine, theophylline, and possibly warfarin. The recommended interval between sucralfate and antacids is 30 minutes. An interval of 1 hour should elapse between giving sucralfate and enteral feeding.

Pharmacokinetics

Sucralfate is only slightly absorbed from the gastrointestinal tract after oral doses. However, there can be some release of aluminium ions and of sucrose sulfate; small quantities of sucrose sulfate may then be absorbed and excreted, primarily in the urine; some absorption of aluminium may also occur (see Renal Impairment, above).

Uses and Administration

Sucralfate is a cytoprotective drug that, under acid gastrointestinal conditions, forms an adherent complex with proteins which coats the gastric mucosa and is reported to have a special affinity for ulcer sites. It also inhibits the action of pepsin and adsorbs bile salts.

Sucralfate has been used in the treatment of peptic ulcer disease (p.1702) and chronic gastritis. It is given orally and should be taken on an empty stomach before meals and at bedtime. The usual dose is 1 g four times daily or 2 g twice daily for 4 to 8 weeks; if necessary the dose may be increased to a maximum of 8 g daily. If longer-term therapy is required sucralfate may be given for up to 12 weeks. Where appropriate a maintenance dose of 1 g twice daily may be given to prevent the recurrence of duodenal ulcers.

For prophylaxis of gastrointestinal haemorrhage from stress ulceration the usual dose of sucralfate is 1 g six times daily; a dose of 8 g daily should not be exceeded. For children's doses see below.

Administration in children. Although sucralfate is not licensed in the UK for use in children under 15 years, the *BNFC* recommends the following oral doses for the treatment of peptic