

Simecon; Simetyl; Sicon; **Turk.:** Antiflat; Metsil; **UAE:** Salinal; **UK:** Asilone Windheaters†; Dentinox; Colic Drops; Infacol; Wind-Eze; **USA:** Baby Gas-X; Colicon; Degas; Extra Strength Minto Plus; Flatulex; Gas Relief; Gas-X; Maalox; Anti-Gas†; Major-Con; Mylanta Gas; Mylicon; Phazyme; SonoRox; **Venez.:** Antiflorm; Flatoril; Sicon†; Silicon†.

Multi-ingredient: numerous preparations are listed in Part 3.

Used as an adjunct in: **Austria:** Prontobarrio; **Cz.:** Prontobarrio†; **Spain:** Bario Dif.

Smectites

СМЕКТИТЫ

ATC — A07BC05 (diosmectite).

ATC Vet — QA07BC05 (diosmectite).

Profile

Smectites are natural mineral clays composed mainly of aluminium silicates and include aluminium magnesium silicate (p.2141), bentonite (p.2141), and Fuller's earth (p.1447). They have adsorbent properties and some, such as dioctahedral smectite (diosmectite), have been used in the management of diarrhoea. They are also used as pharmaceutical excipients and in industry.

References

1. Szajewska H, et al. Meta-analysis: smectite in the treatment of acute infectious diarrhoea in children. *Aliment Pharmacol Ther* 2006; **23**: 217–27.
2. Yen ZS, Lai MS. Smectite for acute diarrhoea in children. *Emerg Med J* 2006; **23**: 65–6.

Preparations

Proprietary Preparations (details are given in Part 3)

Cz.: Smecta; **Fr.:** Smecta; **Ger.:** Colina; **Gr.:** Smecta; **Hong Kong:** Smecta; **Hung.:** Smecta; **Ital.:** Diosmectal; Nodia; **Malaysia:** Smecta; **Pol.:** Smecta; **Rus.:** Smecta (Смекта); **Singapore:** Smecta; **Thai.:** Smecta.

Multi-ingredient: **Belg.:** Baxelax; **Ger.:** Colina Spezial.

Sodium Picosulfate (BAN, rINN)

DA-1773; LA-391; Natrii picosulfas; Natrii Picosulfas Monohydricus; Natrio pikosulfatas; Natriumpikosulfatti; Natriumpikosulfat; Nátrium-pikosulfát; Picosulfate de Sodium; Picosulfate de sodio; Picosulphol; Pikosíran sodný monohydrát; Sodium picosulfate de; Sodium Picosulphate. Disodium 4,4'-(2-pyridylmethylene)-di(phenyl sulphate).

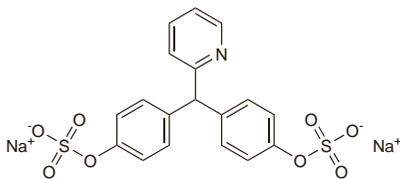
Натрия Пикосульфат

$C_{18}H_{13}NNa_2O_8S_2 \cdot H_2O = 499.4$.

CAS — 10040-45-6.

ATC — A06AB08.

ATC Vet — QA06AB08.



Pharmacopoeias. In *Eur.* (see p.vii) and *Jpn.*

Ph. Eur. 6.2 (Sodium Picosulfate). A white or almost white, crystalline powder. Freely soluble in water; slightly soluble in alcohol.

Adverse Effects and Precautions

As for Bisacodyl, p.1710 and p.1710.

Bowel evacuation. Sodium picosulfate with magnesium citrate was considered a safe and effective bowel cleansing agent in adults¹ and children² with inflammatory bowel disease. They tolerated the preparation as well as patients with other colonic disorders with no adverse effect on their disease symptoms. Patients should be kept well hydrated (it may be appropriate to carry out bowel preparation in hospital in frail or elderly patients to avoid the risks of over- or underhydration^{3,4}), and this procedure should not be used in suspected toxic dilatation of the colon.

In Australia, the Adverse Drug Reactions Advisory Committee has warned that low volume sodium picosulfate solutions may cause marked dehydration, hyponatraemia, other electrolyte abnormalities, and associated complications. Patients at particular risk include infants, the elderly, the frail, and those with congestive heart failure or with renal impairment.⁵

A grand mal seizure in a 64-year-old female given sodium picosulfate with magnesium citrate was assumed to have been caused by hyponatraemia; the patient had normal electrolyte concentra-

tions in the period before taking the bowel preparation. Care is needed when sodium picosulfate solutions are used in those with a low seizure threshold or potential sodium depletion.⁶

1. McDonagh AJG, et al. Safety of Picolax (sodium picosulfate-magnesium citrate) in inflammatory bowel disease. *BMJ* 1989; **299**: 776–7.
2. Evans M, et al. Safety of Picolax in inflammatory bowel disease. *BMJ* 1989; **299**: 1101–2.
3. Lewis M, et al. Bowel preparation at home in elderly people. *BMJ* 1997; **314**: 74.
4. Hanning CD. Bowel preparation at home in elderly people. *BMJ* 1997; **314**: 74.
5. Adverse Drug Reactions Advisory Committee (ADRAC). Electrolyte disturbances with sodium picosulfate bowel cleansing products. *Aust Adverse Drug React Bull* 2002; **21**: 2. Also available at: <http://www.tga.health.gov.au/adr/aadrb/aadr202.pdf> (accessed 03/07/08)
6. Frizelle FA, et al. Hyponatremia and seizures after bowel preparation: report of three cases. *Dis Colon Rectum* 2005; **48**: 393–6.

Pharmacokinetics

Like bisacodyl (p.1710), sodium picosulfate is metabolised by colonic bacteria to the active compound bis(*p*-hydroxyphenyl)pyridyl-2-methane. Only a small amount of sodium picosulfate is absorbed after an oral dose; this is subsequently excreted in the urine.

Uses and Administration

Sodium picosulfate is a stimulant laxative related to bisacodyl (p.1710) used for the treatment of constipation (p.1693) and for evacuation of the colon before investigational procedures or surgery. When taken orally it is metabolised by colonic bacteria to an active form that stimulates bowel movements. It is usually effective within 6 to 12 hours although when used with magnesium citrate for bowel evacuation an effect may be seen within 3 hours.

For constipation it is given as a single oral dose of 5 to 10 mg, usually at bedtime. (For doses in children see below.)

For bowel evacuation, a dose of sodium picosulfate 10 mg with magnesium citrate (p.1743) is given in the morning and again in the afternoon of the day before examination.

Administration in children. In the UK, the following oral doses of sodium picosulfate have been recommended for children in the treatment of constipation; the dose is usually given at night:

- 1 month to 4 years: 250 micrograms/kg (maximum 5 mg)
- 4 to 10 years: 2.5 to 5 mg
- over 10 years: 5 to 10 mg

Most UK licensed product information gives similar doses to those above for **bowel cleansing**. Alternatively, some recommend that children may be given the following doses of a sachet containing sodium picosulfate 10 mg (with magnesium citrate):

- 1 to 2 years: / sachet in the morning and / sachet in the afternoon
- 2 to 4 years: / sachet in the morning and / sachet in the afternoon
- 4 to 9 years: 1 sachet in the morning and / sachet in the afternoon
- over 9 years: 1 sachet in the morning and 1 sachet in the afternoon

Preparations

BP 2008: Compound Sodium Picosulfate Powder for Oral Solution; Sodium Picosulfate Oral Solution.

Proprietary Preparations (details are given in Part 3)

Arg.: Agarol; Cirulaxia; Dagol; Dulcolax; Factor Laxante; Feen-A-Mint; Gotalax; Granulax†; Kritel; Laxamin; Modaton; Modernel†; Opalino; Rapilax; Rogelina†; Trali; Verilax; Yodolin; **Austral.:** Durolax SP; **Austria:** Agaffin; Agiopic; Guttalax; Laxasan; **Belg.:** Dulcolax Picosulphate; Fructines; Guttalax†; Laxoberon; Picolaxine; **Braz.:** Cronoplex; Dilitin; Guttalax; Picolax†; Rapilax; **Chile:** Aguala; Cronolax; Guttalax; Laxantil; Laxoberal; **Cz.:** Agiolax Pico; Darmol†; Guttalax; Laxygal; Progut; Regulax Picosulfat; **Denm.:** Actilax; Laxoberal; Picolon; **Fin.:** Laxoberon; **Fr.:** Fructines; **Ger.:** Agiolax Pico; Darmol Pico; Darmol†; Dulcolax NP; Laxans-ratiopharm Pico; Laxoberal; Liquidepur mit Natriumpicosulfat; Midro Pico†; Regulax Picosulfat; **Gr.:** Guttalax; Laxatol; **Hong Kong:** Sur-Lax; **Hung.:** Darmol; Guttalax; Laxygal; **India:** Cremalax; **Indon.:** Laxoberon; **Irl.:** Dulcolax Perles; Laxoberal; **Ital.:** Eucnessina CM; Falquigut; Gocce Lassative Aicardi; Guttalax; **Jpn.:** Laxoberon; **Mex.:** Anara; Laxoberon; **Neth.:** Dulcodruppels; Dulcoperals; **Norw.:** Laxoberal; **Philipp.:** Laxoberal; **Port.:** Fructines; Guttalax; Laxodal;

Picolax; **Rus.:** Guttalax (Гутталакс); Laxygal (Лаксигал); **Spain:** Contumax; Evacuol; Ezon; Guttalax; Lubrilax; Skilax; **Swed.:** Claxoral; Laxoberal; **Switz.:** Fructines; Laxoberon; **UK:** Dulcolax; Laxoberal; **Venez.:** Lasoberon.

Multi-ingredient: **Arg.:** Agarol; Cascara Sagrada Oligoplex; **Austral.:** Colonprep†; Picolax†; PicoPrep; Prep Kit-C; **Belg.:** Pilules de Vichy; **Braz.:** Agarol; Forlax; **Canad.:** Pico-Salax; **Irl.:** Picolax; **Malaysia:** PicoPrep; **NZ:** PicoPrep; **Spain:** Emuliquen Laxante; **Switz.:** Laxasan; **UK:** CitraFleet; Picolax.

Anhydrous Sodium Sulfate

Anhydrous Sodium Sulphate; Dried Sodium Sulphate; Exsiccated Sodium Sulphate; Natrii Sulfas; Natrii sulfas anhydricus; Natrio sulfatas; bevandenis; Natrium Sulfuricum Siccatum; Natriumsulfaatti; vedetön; Natriumsulfat, vattenfritt; Síran sodný; Sodium (sulfate de) anhydre; Sodu siarczan bezwodny; Sulfato de sodio anhidro; Vízmentes nátrium-szulfát.

Безводный Сульфат Натрия

$Na_2SO_4 = 142.0$.

CAS — 7757-82-6.

ATC — A06AD13; A12CA02.

ATC Vet — QA06AD13; QA12CA02.

Pharmacopoeias. In *Chin.*, *Eur.* (see p.vii), *Int.*, and *Viet.*

US includes a single monograph for both the anhydrous form and the decahydrate.

Ph. Eur. 6.2 (Sodium Sulphate, Anhydrous). A white or almost white, hygroscopic powder. Freely soluble in water. Store in airtight containers.

USP 31 (Sodium Sulfate). It contains 10 molecules of water of hydration or is anhydrous. The decahydrate loses between 51 and 57% of its weight on drying and the anhydrous form loses not more than 0.5% of its weight. Large, colourless, odourless, transparent crystals or a granular powder. It effloresces rapidly in air, liquefies in its water of hydration at about 33°, and loses all of its water of hydration at about 100°. Freely soluble in water; insoluble in alcohol; soluble in glycerol. Store in airtight containers, preferably at a temperature not exceeding 30°.

Sodium Sulfate

E514; Glauber's Salt; Natrii sulfas decahydricus; Natrii Sulphas; Natrio sulfatas decahydricus; Natrium Sulfuricum Crystallissimum; Natriumsulfaattidekahydraatti; Natriumsulfatedekahydrat; Nátrium-szulfát-dekahidrátt; Síran sodný dekahydrát; Sodium (sulfate de) décahydraté; Sodium Sulphate; Sodium Sulphate Decahydrate; Sodu siarczan dziesięciowodny; Sulfato de sodio.

Глауберова соль; Сульфат Натрия

$Na_2SO_4 \cdot 10H_2O = 322.2$.

CAS — 7727-73-3 (sodium sulfate decahydrate).

ATC — A06AD13; A12CA02.

ATC Vet — QA06AD13; QA12CA02.

Pharmacopoeias. In *Chin.*, *Eur.* (see p.vii), *Int.*, and *Viet.*

US includes a single monograph for both the anhydrous form and the decahydrate.

Ph. Eur. 6.2 (Sodium Sulphate Decahydrate; Sodium Sulphate BP 2008). A white or almost white, crystalline powder or colourless, transparent crystals. Freely soluble in water; practically insoluble in alcohol. It partly dissolves in its own water of crystallisation at about 33°. It loses between 52.0 and 57.0% of its weight on drying.

USP 31 (Sodium Sulfate). It contains 10 molecules of water of hydration or is anhydrous. The decahydrate loses between 51 and 57% of its weight on drying and the anhydrous form loses not more than 0.5% of its weight. Large, colourless, odourless, transparent crystals or a granular powder. It effloresces rapidly in air, liquefies in its water of hydration at about 33°, and loses all of its water of hydration at about 100°. Freely soluble in water; insoluble in alcohol; soluble in glycerol. Store in airtight containers, preferably at a temperature not exceeding 30°.

Profile

Sodium sulfate has been used as an osmotic laxative (p.1693). It is also given in dilute solution (about 0.5%) with a high molecular weight macrogol for prompt bowel evacuation before investigational procedures or surgery (see Macrogols, p.2336).

Sodium sulfate is also used as an additive in foods.

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

Preparations

USP 31: Sodium Sulfate Injection.

Proprietary Preparations (details are given in Part 3)

Austral.: Celloids SS 69.

Multi-ingredient: **Arg.:** Magnesia Phosphorica I Oligoplex; **Austral.:** Duo Celloids SPSS; Duo Celloids SSMP; Duo Celloids SSPC; Duo Celloids SSS; Iron Compound†; Liv-Detox†; Silybum Complex†; **Canad.:** Normo Gastryl; **Fr.:** Actisoufre; Digidryl; Hepargitol; Normogastryl†; Oxyboldine; Prefagy†; **Ital.:** Argioferdina†; **Pol.:** Sal Em's Artificialia; Sal Em's Factium†; Sal Vichy Factium†; **Spain:** Darnen Salt; Digestovital†; Leberite; Lebersal; Salcedol; **Switz.:** Padma-Lax; Padmed Laxan; **Thai.:** Ulgastrin; **USA:** Triv; **Venez.:** Topdent†.

The symbol † denotes a preparation no longer actively marketed