Potassium Acid Tartrate

E336; Hydrogenvinan draselný; Kalii hydrogenotartras; Kaliovandenilio tartratas; Kalium Hydrotartaricum; Kálium-hidrogéntartarát; Kaliumvätetartrat; Kaliumvetytartraatti; Potassium Bitartrate *(USAN)*; Potassium Hydrogen Tartrate; Potassium, hydrogénotartrate de; Potasu wodorowinian; Purified Cream of Tartar; Tartarus Depuratus; Tartrato ácido de potasio; Weinstein.

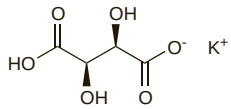
Кислый Виннокислый Калий

$C_4H_5KO_6$ = 188.2.

CAS — 868-14-4.

ATC — A12BA03.

ATC Vet — QA12BA03.



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

Ph. Eur. 6.2 (Potassium Hydrogen Tartrate). A white or almost white, crystalline powder or colourless crystals. Slightly soluble in water; practically insoluble in alcohol. It dissolves in dilute solutions of mineral acids and alkali hydroxides.

USP 31 (Potassium Bitartrate). Colourless or slightly opaque crystals or a white, crystalline powder. Slightly soluble in water; soluble in boiling water; very slightly soluble in alcohol. A saturated solution is acid to litmus. Store in airtight containers.

Profile

Potassium acid tartrate is given with sodium bicarbonate as a suppository for the treatment of constipation (p.1693) and for bowel evacuation before investigational procedures or surgery. Carbon dioxide gas is produced in the rectum, which stimulates defaecation within 5 to 30 minutes.

Potassium acid tartrate is used as a food additive and pharmaceutical aid.

Potassium acid tartrate has been used as an ingredient of preparations for potassium supplementation, although other potassium salts are usually preferred. For the general properties of potassium salts, see p.1684.

Preparations

BPC 1968: Effervescent Potassium Tablets.

Proprietary Preparations (details are given in Part 3)

Multi-ingredient: ***Austria:*** Lecicarbon; ***Braz.:*** Circanetten†; Varicell†; ***Ital.:*** Potassion; ***Swed.:*** Relaxit; ***Thai.:*** Circanetten; ***USA:*** Ceo-Two.

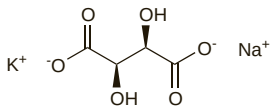
Potassium Sodium Tartrate

E337; Kalii natrii tartras; Kalio-natrio tartratas; Kalium Natrium Tartaricum; Kálium-nátrium-tartarát; Kaliumnatriumtartraatti; Kaliumnatriumtartrat; Potassium et de sodium, tartrate de; Rochelle Salt; Seignette Salt; Sodii et Potassii Tartras; Sodium Potassium Tartrate; Sodu potasu winian; Tartarus Natronatus; Tartrato de potasio y de sodio; Vinan draselno-sodný.

Виннокислый Калий-натрий

$C_4H_4KNaO_6.4H_2O$ = 282.2.

CAS — 304-59-6 (anhydrous sodium potassium tartrate); 6381-59-5 (sodium potassium tartrate tetrahydrate); 6100-16-9 (sodium potassium tartrate tetrahydrate).



(anhydrous sodium potassium tartrate)

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

Ph. Eur. 6.2 (Potassium Sodium Tartrate Tetrahydrate). A white or almost white, crystalline powder or colourless transparent crystals. Very soluble in water; practically insoluble in alcohol.

USP 31 (Potassium Sodium Tartrate). Colourless crystals or a white, crystalline powder, with a cooling, saline taste. It effloresces slightly in warm dry air, the crystals often being coated with a white powder. Soluble 1 in 1 of water; practically insoluble in alcohol. Store in airtight containers.

Profile

Potassium sodium tartrate has been used as an osmotic laxative (p.1693). It is also used as a food additive.

For the general properties of potassium salts, see p.1684, and of sodium salts, see p.1686.

Preparations

BPC 1973: Compound Effervescent Powder.

Proprietary Preparations (details are given in Part 3)

Gr.: Trigolax.

Multi-ingredient: ***Austria:*** Laxalpin; ***Fr.:*** Romarene; ***Philipp.:*** Castoria; ***UK:*** Jaaps Health Salt.

Prifinium Bromide *(rINN)*

Bromuro de prifinio; PDB; Prifinii Bromidum; Prifinium, Bromure de; Pyrodifenium Bromide. 3-Diphenylmethylene-1,1-diethyl-2-methylpyrrolidinium bromide.

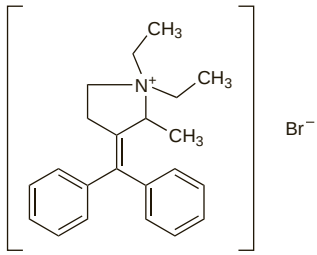
Прифиния Бромид

$C_{22}H_{28}BrN$ = 386.4.

CAS — 10236-81-4 (prifinium); 4630-95-9 (prifinium bromide).

ATC — A03AB18.

ATC Vet — QA03AB18.



Profile

Prifinium bromide is a quaternary ammonium antimuscarinic with peripheral effects similar to those of atropine (p.1219). It is structurally related to diphemanil metilsulfate (p.2295).

Prifinium bromide is used to relieve smooth muscle spasms. Oral doses usually range from 90 to 180 mg daily in 3 divided doses. It has also been given rectally in a dose of 60 mg three or four times daily, or by subcutaneous, intramuscular, or intravenous injection in a dose of 15 mg given 2 to 4 times daily.

Preparations

Proprietary Preparations (details are given in Part 3)

Fr.: Riabal†; ***Ital.:*** Riabal; ***Jpn:*** Padrin†; ***Mex.:*** Anespas; ***Rus.:*** Riabal (Риабал); ***Thai.:*** Riabal†.

Proglumide *(BAN, USAN, rINN)*

CR-242; Proglumida; Proglumidum; W-5219; Xylamide. (±)-4-Benzamido-*N*,*N*-dipropylglutaramic acid.

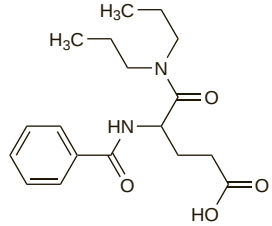
Проглумид

$C_{18}H_{26}N_2O_4$ = 334.4.

CAS — 6620-60-6.

ATC — A02BX06.

ATC Vet — QA02BX06.



Pharmacopoeias. In *Chin.* and *Jpn*.

Profile

Proglumide is a cholecystokinin antagonist with an inhibitory effect on gastric secretion. It has been used in the treatment of peptic ulcer disease (p.1702) and other gastrointestinal disorders in usual doses of 400 mg two to four times daily by mouth before meals; up to 800 mg three times daily may be given. It has also been given by intramuscular or intravenous injection in a dose of 400 to 800 mg daily.

Preparations

Proprietary Preparations (details are given in Part 3)

Austria: Milid; ***Ital.:*** Milid†; ***Port.:*** Milid†.

Propantheline Bromide *(BAN, rINN)*

Bromuro de propantelina; Propanteliinibromidi; Propantelin Bromür; Propantelinbromid; Propantelin-bromid; Propantelino bromidas; Propanthéline, bromure de; Propanthelini bromidum; Propanthelinii Bromidum; Propanthelinium-bromid. Di-isopropylmethyl[2-(xanthen-9-ylcarbonyloxy)ethyl]ammonium bromide.

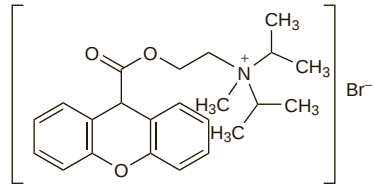
Пропантелина Бромид

$C_{23}H_{30}BrNO_3$ = 448.4.

CAS — 298-50-0 (propantheline); 50-34-0 (propantheline bromide).

ATC — A03AB05.

ATC Vet — QA03AB05.



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

Ph. Eur. 6.2 (Propantheline Bromide). A white or yellowish-white, slightly hygroscopic powder. Very soluble in water, in alcohol, and in dichloromethane. Store in airtight containers.

USP 31 (Propantheline Bromide). White or practically white, odourless, crystals. Very soluble in water, in alcohol, and in chloroform; practically insoluble in ether and in benzene.

Adverse Effects, Treatment, and Precautions

As for Atropine Sulfate, p.1219. Contact dermatitis has been reported after topical application of propantheline bromide.

Buccal and oesophageal ulceration. Severe buccal mucosal ulceration has been reported[1] in a 95-year-old woman as a result of retaining emepronium bromide tablets in her mouth, and recurred on giving propantheline bromide tablets.

1. Huston GJ, *et al*. Anticholinergic drugs, buccal ulceration and mucosal potential difference. *Postgrad Med J* 1978; **54:** 331–2.

Interactions

As for antimuscarinics in general (see Atropine Sulfate, p.1220).

Pharmacokinetics

Propantheline bromide is incompletely absorbed from the gastrointestinal tract and bioavailability is reported to be reduced by food; it is extensively metabolised in the small intestine before absorption. The plasma elimination half-life after a single oral dose has been reported to be about 2 to 3 hours. Propantheline is eliminated mainly in the urine as metabolites and less than 10% as unchanged drug. The duration of action is about 6 hours.

Uses and Administration

Propantheline bromide is a quaternary ammonium antimuscarinic with peripheral effects similar to those of atropine (p.1219). It has been used as an antispasmodic (p.1692) for conditions associated with gastrointestinal spasm, and as an adjunct in the treatment of peptic ulcer disease (p.1702). The usual initial oral dose is 15 mg three times daily, 30 to 60 minutes before meals, and 30 mg at bedtime; doses of up to 120 mg daily may be needed in some patients. In elderly patients, doses of 7.5 mg three times daily may be sufficient. Doses of 300 micrograms/kg (to a maximum of 15 mg) given 3 or 4 times daily have been used for the relief of gastrointestinal spasm in children aged 1 month to 12 years; older children may be given the adult dose.

Propantheline bromide has been used in the treatment of adult enuresis or urinary incontinence, and in hyperhidrosis (see below), in doses similar to those given above.

Hyperhidrosis. Some antimuscarinics, including propantheline, have been applied topically in the treatment of hyperhidrosis (p.1580). Adverse effects of antimuscarinics given by mouth generally preclude their use by this route, although oral propantheline was used successfully to control excessive sweating in 2

patients with spinal cord injuries,[1] and it is sometimes used in palliative care to control night sweats. The *BNF* notes that propantheline may be used for gustatory sweating in patients with diabetic neuropathy.

1. Canaday BR, Stanford RH. Propantheline bromide in the management of hyperhidrosis associated with spinal cord injury. *Ann Pharmacother* 1995; **29:** 489–92.

Urinary incontinence. In the UK, guidelines issued by NICE suggest that propantheline should not be recommended for the treatment of urinary incontinence (p.2180) or overactive bladder in women; other antimuscarinics are preferred.[1]

1. National Institute for Health and Clinical Excellence. Urinary incontinence: the management of urinary incontinence in women (issued October 2006). Available at: http://www.nice.org.uk/nicemedia/pdf/CG40fullguideline.pdf (accessed 03/07/08)

Preparations

BP 2008: Propantheline Tablets;
USP 31: Propantheline Bromide Tablets.

Proprietary Preparations (details are given in Part 3)
Austral.: Pro-Banthine; ***Canad.:*** Propanthel†; ***Denm.:*** Erconil; ***India:*** Pro-Banthine; ***Indon.:*** Pro-Banthine; ***Mex.:*** Propantel†; ***NZ:*** Pro-Banthine; ***S.Afr.:*** Pro-Banthine; ***UK:*** Pro-Banthine; ***USA:*** Pro-Banthine.

Multi-ingredient: ***Indon.:*** Methaphyllin; ***Ital.:*** Lexil.

Prune

Ameixa; Ciruela; Prunus.

Слива Домашняя (*Prunus domestica*)

Profile

Prune is the dried ripe fruits of the plum *Prunus domestica* and some other species of *Prunus* (Rosaceae). It has laxative and demulcent properties.

◊ References.

1. Stacewicz-Sapuntzakis M, *et al.* Chemical composition and potential health effects of prunes: a functional food? *Crit Rev Food Sci Nutr* 2001; **41:** 251–86.

Preparations

Proprietary Preparations (details are given in Part 3)
Mex.: Viviolax†.

Multi-ingredient: ***Arg.:*** Cirulaxia; Mermelax; ***Austral.:*** Neo-Cleanse; Prolax†; ***Canad.:*** Fruitatives†; ***Chile:*** Tamarine; ***Fr.:*** Carres Parapsyllium; Laxarine; ***Mex.:*** Ciruelax Jalea; Laxacaps.

Rabeprazole Sodium *(BANM, USAN, rINNM)*

E-3810; LY-307640; Natrii Rabeprazolum; Rabeprazol sódico; Rabeprazol Sodyum; Rabéprazole sodique; Rabeprazolum natricum; Sodium Pariprazole. 2-({[4-(3-Methoxypropoxy)-3-methyl-2-pyridyl]methyl}sulfinyl)-1*H*-benzimidazole sodium.

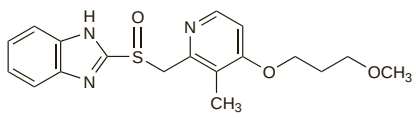
Натрий Рабепразол

$C_{18}H_{20}N_3NaO_3S$ = 381.4.

CAS — 117976-89-3 (rabeprazole); 117976-90-6 (rabeprazole sodium).

ATC — A02BC04.

ATC Vet — QA02BC04.



(rabeprazole)

Adverse Effects and Precautions

As for Omeprazole, p.1753.

Effects on the endocrine system. For cases of gynaecomastia associated with rabeprazole see p.1753.

Effects on the kidneys. For reports of interstitial nephritis associated with rabeprazole see p.1753.

Effects on the nervous system. For a report of neuropsychiatric symptoms associated with rabeprazole, see under Omeprazole, p.1754.

Interactions

As for Omeprazole (p.1755) but clinically significant interactions with diazepam, phenytoin, theophylline, or warfarin have not been found in healthy subjects.

Pharmacokinetics

Rabeprazole is rapidly absorbed and peak plasma concentrations are reached about 3.5 hours after an oral dose. The oral bioavailability is about 52% with the enteric-coated tablet formulation, because of first-pass metabolism, and does not appear to vary after single or repeated doses. Rabeprazole is about 97% bound to plasma proteins. It is extensively metabolised in the liver by cytochrome P450 isoenzymes CYP2C19 and CYP3A4 to the thioether, thioether carboxylic acid, sulfone, and desmethylthioether. Metabolites are excreted principally in the urine (about 90%) with the remainder in the faeces. The plasma half-life is about 1 hour, increased two to threefold in hepatic impairment, 1.6 times in CYP2C19 slow metabolisers (see also Metabolism under Omeprazole, p.1755), and by 30% in the elderly.

◊ References.

1. Yasuda S, *et al.* Comparison of the kinetic disposition and metabolism of E3810, a new proton pump inhibitor, and omeprazole in relation to S-mephenytoin 4-hydroxylation status. *Clin Pharmacol Ther* 1995; **58:** 143–54.
2. Keane WF, *et al.* Rabeprazole: pharmacokinetics and tolerability in patients with stable, end-stage renal failure. *J Clin Pharmacol* 1999; **39:** 927–33.

Uses and Administration

Rabeprazole is a proton pump inhibitor with actions and uses similar to those of omeprazole (p.1755). It is given orally as rabeprazole sodium in the form of enteric-coated tablets. It is normally taken in the morning.

In the treatment of severe (erosive or ulcerative) **gastro-oesophageal reflux disease** (p.1696), the usual dose of rabeprazole sodium is 20 mg once daily for 4 to 8 weeks; in the USA, a further 8-week course is permitted for healing of erosive oesophagitis. Thereafter, maintenance therapy can be continued with 10 or 20 mg daily depending on the response. For symptomatic disease without erosive or ulcerative oesophagitis a dose of 10 or 20 mg may be given once daily for 4 weeks; in the USA, a further 4-week course is permitted. Once symptoms have resolved, a dose of 10 mg once daily may be given as necessary.

For the treatment of active **peptic ulcer disease** (p.1702), 20 mg daily is given for 4 to 8 weeks for duodenal ulcer and 6 to 12 weeks for gastric ulcer. For the eradication of *Helicobacter pylori* rabeprazole sodium may be combined with two antibacterials in a 1-week **triple therapy** regimen. Effective regimens include 20 mg twice daily combined with clarithromycin 500 mg twice daily and amoxicillin 1 g twice daily, or combined with clarithromycin 250 mg twice daily and metronidazole 400 mg twice daily.

For **Zollinger-Ellison syndrome** (p.1704), the starting dose is 60 mg once daily, adjusted according to response. Doses up to 120 mg daily have been given; when the daily dose is more than 100 mg it should be given in 2 divided doses.

◊ Reviews.

1. Prakash A, Faulds D. Rabeprazole. *Drugs* 1998; **55:** 261–7.
2. Anonymous. Rabeprazole. *Med Lett Drug Ther* 1999; **41:** 110–12.
3. Carswell CI, Goa KL. Rabeprazole: an update of its use in acid-related disorders. *Drugs* 2001; **61:** 2327–2356.

Preparations

Proprietary Preparations (details are given in Part 3)
Arg.: Pariet; Rabec; ***Austral.:*** Pariet; ***Austria:*** Pariet; ***Belg.:*** Pariet; ***Braz.:*** Pariet; ***Canad.:*** Pariet; ***Chile:*** Gastrodine; ***Denm.:*** Pariet; ***Fin.:*** Pariet; ***Fr.:*** Pariet; ***Ger.:*** Pariet; ***Gr.:*** Pariet; ***Hong Kong:*** Pariet; ***Hung.:*** Pariet; ***India:*** Odirab; Rabeloc; Rabicip; ***Indon.:*** Pariet; ***Irl.:*** Pariet; ***Ital.:*** Pariet; ***Jpn:*** Pariet; ***Malaysia:*** Pariet; ***Mex.:*** Pariet; ***Neth.:*** Pariet; ***Philipp.:*** Pariet; ***Pol.:*** Pariet; ***Port.:*** Pariet; ***Rus.:*** Pariet (Париет); ***S.Afr.:*** Pariet; ***Singapore:*** Pariet; ***Spain:*** Aciphex; Pariet; ***Swed.:*** Pariet; ***Switz.:*** Pariet; ***Thai.:*** Pariet; ***Turk.:*** Pariet; ***UK:*** Pariet; ***USA:*** Aciphex; ***Venez.:*** Pariet.

Racecadotril *(rINN)*

Acetorphan; Racécadotril; Racecadotrilo; Racecadotrilum. (±)-*N*-{2-[(Acetylthio)methyl]-1-oxo-3-phenylpropyl}glycine phenylmethyl ester; *N*-[(*R,S*)-3-acetylthio-2-benzylpropanoyl]glycine benzyl ester; (±)-*N*-[α-(Mercaptomethyl)hydrocinnamoyl]glycine benzyl ester acetate.

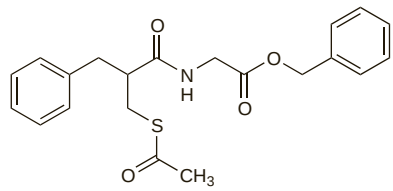
Рацекадотрил

$C_{21}H_{23}NO_4S$ = 385.5.

CAS — 81110-73-8.

ATC — A07XA04.

ATC Vet — QA07XA04.



Pharmacopoeias. In *Eur.* (see p.vii).
Ph. Eur. 6.2 (Racecadotril). A white or almost white powder. Practically insoluble in water; freely soluble in methyl alcohol and in dichloromethane.

Profile

Racecadotril is an enkephalinase inhibitor that inhibits the breakdown of endogenous opioids, thus reducing intestinal secretions. It is given orally in doses of 100 mg three times daily before meals for up to 7 days for the symptomatic management of acute diarrhoea (p.1694).

The *S*-form of racecadotril (sinorphan, ecadotril—see Natriuretic Peptides, p.1347) has been investigated for hypertension and heart failure.

◊ References.

1. Baumer P, *et al.* Effects of acetorphan, an enkephalinase inhibitor, on experimental and acute diarrhoea. *Gut* 1992; **33:** 753–8.
2. Roge J, *et al.* The enkephalinase inhibitor, acetorphan, in acute diarrhoea: a double-blind, controlled clinical trial versus Loperamide. *Scand J Gastroenterol* 1993; **28:** 352–4.
3. Beaugerie L, *et al.* Treatment of refractory diarrhoea in AIDS with acetorphan and octreotide: a randomized crossover study. *Eur J Gastroenterol Hepatol* 1996; **8:** 485–9.
4. Salazar-Lindo E, *et al.* Racecadotril in the treatment of acute watery diarrhea in children. *N Engl J Med* 2000; **343:** 463–7.
5. Matheson AJ, Noble S. Racecadotril. *Drugs* 2000; **59:** 829–35.
6. Alam NH, *et al.* Efficacy and tolerability of racecadotril in the treatment of cholera in adults: a double blind, randomised, controlled clinical trial. *Gut* 2003; **52:** 1419–23.
7. Wang H-H, *et al.* A blind, randomized comparison of racecadotril and loperamide for stopping acute diarrhea in adults. *World J Gastroenterol* 2005; **11:** 1540–3.
8. Szajewska H, *et al.* Systematic review: racecadotril in the treatment of acute diarrhoea in children. *Aliment Pharmacol Ther* 2007; **26:** 807–13.

Preparations

Proprietary Preparations (details are given in Part 3)
Braz.: Tiorfan; ***Fr.:*** Tiorfan; ***Ger.:*** Tiorfan; ***Gr.:*** Hidrasec; ***Indon.:*** Hidrasec; ***Mex.:*** Hidrasec; ***Port.:*** Tiorfan; ***Spain:*** Tiorfan; ***Thai.:*** Hidrasec†; ***Venez.:*** Hidrasec.

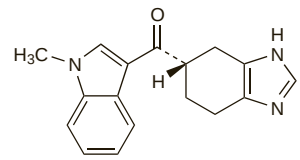
Ramosetron Hydrochloride *(rINNM)*

Hidrocloruro de ramosetrón; Ramosétron, Chlorhydrate de; Ramosetroni Hydrochloridum; YM-060. (–)-(*R*)-1-Methylindol-3-yl 4,5,6,7-tetrahydro-5-benzimidazolyl ketone hydrochloride.

Рамосетрона Гидрохлорид

$C_{17}H_{17}N_3O,HCl$ = 315.8.

CAS — 132036-88-5 (ramosetron); 132907-72-3 (ramosetron hydrochloride).



(ramosetron)

Profile

Ramosetron is a 5-HT_3 antagonist with general properties similar to those of ondansetron (p.1756). Ramosetron hydrochloride is given for its antiemetic properties in the management of nausea and vomiting induced by cancer chemotherapy in usual doses of 300 micrograms once daily intravenously, or 100 micrograms once daily by mouth. Ramosetron is also under investigation in the management of diarrhoea-predominant irritable bowel syndrome.

Preparations

Proprietary Preparations (details are given in Part 3)
Indon.: Nasea; ***Jpn:*** Nasea; ***Philipp.:*** Nasea; ***Thai.:*** Nasea.