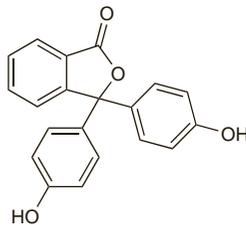


Phenolphthalein (BAN, rINN)

Dihydroxyphthalophenone; Fenolfaltalein; Fenolfaltaleína; Fenolfaltaleinas; Fenolfaltaleini; Fenolfoftaleína; Phénolphthaléine; Phenolphthaleinum; Phenolphthaleinum. 3,3-Bis(4-hydroxyphenyl)-phthalide.

Фенолфталейн
C₂₀H₁₄O₄ = 318.3.
CAS — 77-09-8.
ATC — A06AB04.
ATC Vet — QA06AB04.



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

Ph. Eur. 6.2 (Phenolphthalein). A white or almost white powder. Practically insoluble in water; soluble in alcohol. Protect from light.

Adverse Effects and Precautions

As for Bisacodyl, p.1710. Hypersensitivity reactions, usually as skin rashes or eruptions, have occurred with phenolphthalein. Phenolphthalein may cause pink discoloration of alkaline urine. Tumours have occurred in *rats* and *mice* given very high doses of phenolphthalein; there does not appear to be evidence of carcinogenicity in humans, but phenolphthalein-containing products have been withdrawn in many countries because of concerns about long-term safety.

Effects on the skin. Reports of skin reactions associated with phenolphthalein include fixed drug eruptions,^{1,2} erythema multiforme reactions,^{1,3} and toxic epidermal necrolysis.^{4,5}

1. Baer RL, Harris H. Types of cutaneous reactions to drugs. *JAMA* 1967; **202**: 710-13.
2. Savin JA. Current causes of fixed drug eruptions. *Br J Dermatol* 1970; **83**: 546-9.
3. Shelley WB, et al. Demonstration of intercellular immunofluorescence and epidermal hysteresis in bullous fixed drug eruption due to phenolphthalein. *Br J Dermatol* 1972; **86**: 118-25.
4. Kar PK, et al. Toxic epidermal necrolysis in a patient induced by phenolphthalein. *J Indian Med Assoc* 1986; **84**: 189-93.
5. Artymowicz RJ, et al. Phenolphthalein-induced toxic epidermal necrolysis. *Ann Pharmacother* 1997; **31**: 1157-9.

Overdosage. The most likely consequence of phenolphthalein overdosage is excessive purgation, which may require fluid and electrolyte replacement. However, a possible association with acute pancreatitis occurred in a 34-year-old man who inadvertently ingested phenolphthalein 2 g. There was complete recovery with no sequelae from the pancreatitis.¹ Widespread organ failure with disseminated intravascular coagulation, massive liver damage, pulmonary oedema, renal failure, and myocardial damage in a second patient² were attributed to self-poisoning with an unknown quantity of phenolphthalein-containing laxative, although the diagnosis was problematic. The patient died despite intensive support.

1. Lambrianides AL, Rosin RD. Acute pancreatitis complicating excessive intake of phenolphthalein. *Postgrad Med J* 1984; **60**: 491-2.
2. Sidhu PS, et al. Fatal phenolphthalein poisoning with fulminant hepatic failure and disseminated intravascular coagulation. *Hum Toxicol* 1989; **8**: 381-4.

Pharmacokinetics

Up to 15% of phenolphthalein given orally is subsequently excreted in the urine. Enterohepatic circulation occurs and the glucuronide is excreted in the bile. Elimination may take several days.

Uses and Administration

Phenolphthalein is a diphenylmethane stimulant laxative that has been used for the treatment of constipation (p.1693) and for bowel evacuation before investigational procedures or surgery. It has been withdrawn in many countries because of concern over its carcinogenic potential after reports of tumours in *rodents*.

It has been given in pills or tablets, and as an emulsion with liquid paraffin. Yellow phenolphthalein, an impure form, has been used similarly.

Preparations

Proprietary Preparations (details are given in Part 3)

Arg.: Fructines; **Chile:** Relaxent; **Cz.:** Confitto Falqui; **Israel:** EasyLax; **S.Afr.:** Brooklax; Dr Mackenzie's Veinoids; Laxador; Laxene; Laxicaps P; SB Strong-Lax; Super-Tabs; Surgel; **Singapore:** Regulim; **Switz.:** Regulets; **Thai.:** Purnmolax; Regulim; **Turk.:** Alin; Laksafenol; **Venez.:** Agarolax.

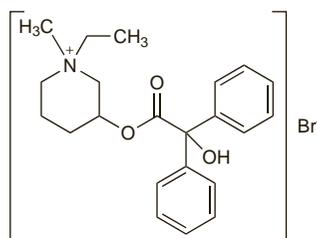
Multi-ingredient: **Arg.:** Cascara Sagrada Bouzen; Cascara Sagrada Pulver; Genolaxante; Veracolate; **Austral.:** Ford Pills; **Austria:** Waldheim Abführdragees forte; **Belg.:** Grains de Vals; **Braz.:** Emagrex; Fenogar; Manoli; Obesidex; Obesifran; Prisoventril; **Chile:** Agarol; Bulgarolax; Fenokomp 39; Fenolfaltaleina Compuesta; Oblax A-1-1; **Ger.:** Vencipon N; **Hung.:** Artin; Bilagit; **India:** Agarol; Jetomisol-P; **Indon.:** Laxadine;

Israel: Laxative; Laxative Comp; **Port.:** Byfi; Caroid; **S.Afr.:** Brooklax; Pills; Redupon; SB 3 Triple Action Pills; Veracolate; **Spain:** Laxante Bescansa Aloico; Mahiou; **Switz.:** Paragar; **Thai.:** Emulax; Veracolate; Zenda; **Turk.:** Karboplast; Musilaks; **UK:** Fam-Lax; **USA:** Agoral; Doxidant; **Venez.:** Agarol.

Pipenzolate Bromide (BAN, rINN)

Bromuro de pipenzolato; Pipenzolat Bromür; Pipenzolate, Bromure de; Pipenzolate Methylbromide; Pipenzolati Bromidum. 3-Benziloyloxy-1-ethyl-1-methylpiperidinium bromide.

Пипензолат Бромид
C₂₂H₂₈BrNO₃ = 434.4.
CAS — 13473-38-6 (pipenzolate); 125-51-9 (pipenzolate bromide).
ATC — A03AB14.
ATC Vet — QA03AB14.

**Profile**

Pipenzolate bromide is a quaternary ammonium antimuscarinic with peripheral actions similar to those of atropine (p.1219). It has been used as an adjunct in the treatment of gastrointestinal disorders characterised by smooth muscle spasm.

Preparations

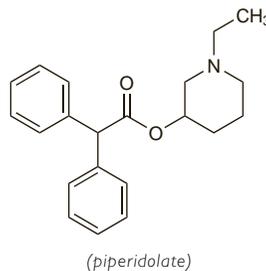
Proprietary Preparations (details are given in Part 3)

Ger.: Ila-med m; **Mex.:** Expal; Pipzen; **Turk.:** Piptalin.
Multi-ingredient: **Chile:** Baldmin; Gasorbol; Sinpasmon; **Indon.:** Piptal; **Mex.:** Espasal; Espasint; Expal Compuesto; Finprob; **Turk.:** Asilon; Libkol; **UAE:** Alinal.

Piperidolate Hydrochloride (BANM, rINN)

Hydrocloruro de piperidolato; Pipéridolate, Chlorhydrate de; Piperidolati Hydrochloridum. 1-Ethyl-3-piperidyl diphenylacetate hydrochloride.

Пиперидолат Гидрохлорид
C₂₁H₂₅NO₂·HCl = 359.9.
CAS — 82-98-4 (piperidolate); 129-77-1 (piperidolate hydrochloride).
ATC — A03AA30.
ATC Vet — QA03AA30.

**Profile**

Piperidolate hydrochloride is a tertiary amine antimuscarinic with effects similar to those of atropine (p.1219). It has been given in the symptomatic treatment of smooth muscle spasm associated with gastrointestinal disorders.

Preparations

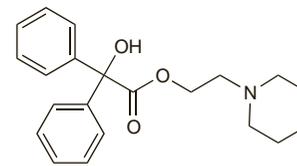
Proprietary Preparations (details are given in Part 3)

Mex.: Dactil OB.
Multi-ingredient: **Braz.:** Dactil OB.

Pipethanate Ethobromide (rINN)

Ethylpipethanate Bromide; Etobromuro de pipetanato; Piperilate Ethobromide; Pipéthanate, Ethobromure de; Pipethanati Ethobromidum. 1-(2-Benziloyloxyethyl)-1-ethylpiperidinium bromide.

Пипетанат Этобромид
C₂₃H₃₀BrNO₃ = 448.4.
CAS — 4546-39-8 (pipethanate); 23182-46-9 (pipethanate ethobromide).



(pipethanate)

Profile

Pipethanate ethobromide is an antimuscarinic with actions similar to those of atropine (p.1219). It has been used in the symptomatic treatment of visceral spasms in oral doses of up to 160 mg daily in divided doses. Pipethanate ethobromide has also been given intramuscularly or intravenously in doses of 10 to 20 mg daily and rectally in doses of 60 or 120 mg daily.

Preparations

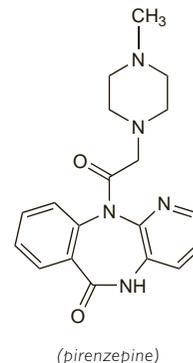
Proprietary Preparations (details are given in Part 3)

Chile: Nospasmin; **Ital.:** Spasmodil; **Jpn.:** Panpurof.
Multi-ingredient: **Chile:** Nospasmin Compuesto.

Pirenzepine Hydrochloride (BANM, USAN, rINN)

Hydrocloruro de pirenzepina; LS-519 (pirenzepine); LS-519-Cl₂; Pirentsepiindihydrokloridmonohydraatti; Pirenzepin-dihydrokloridmonohidrát; Pirenzepin-dihydrochlorid monohydrát; Pirenzepindihydrokloridmonohydrát; Pirenzepine, Chlorhydrate de; Pirenzepine (dichlorhydrate de) monohydrate; Pirenzepini dihydrochloridum monohydricum; Pirenzepini Hydrochloridum; Pirenzepino dihydrochloridas monohidratas. 5,11-Dihydro-11-(4-methylpiperazin-1-ylacetyl)pyrido[2,3-b][1,4]benzodiazepin-6-one dihydrochloride monohydrate.

Пирензепина Гидрохлорид
C₁₉H₂₁N₅O₂·2HCl·H₂O = 442.3.
CAS — 28797-61-7 (pirenzepine); 29868-97-1 (pirenzepine hydrochloride).
ATC — A02BX03.
ATC Vet — QA02BX03.



(pirenzepine)

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

Ph. Eur. 6.2 (Pirenzepine Dihydrochloride Monohydrate; Pirenzepine Hydrochloride BP 2008). A white or yellowish crystalline powder. Freely soluble in water; very slightly soluble in dehydrated alcohol; practically insoluble in dichloromethane; slightly soluble in methyl alcohol. A 10% solution in water has a pH of 1.0 to 2.0. Protect from light.

Adverse Effects and Precautions

Dry mouth and blurred vision have been reported but the risk of antimuscarinic effects (see Atropine Sulfate, p.1219) may be reduced. Pirenzepine should be used with caution in patients with renal impairment, particularly those with end-stage renal failure.

Effects on the blood. Thrombocytopenia in one patient and agranulocytosis in another was probably associated with the use of pirenzepine.¹

1. Stricker BHC, et al. Blood disorders associated with pirenzepine. *BMJ* 1986; **293**: 1074.

Interactions

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

Pharmacokinetics

Pirenzepine is absorbed from the gastrointestinal tract but the bioavailability is reported to be only about 20 to 30%, and is decreased to about 10 to 20% when taken with food. Very little pirenzepine is metabolised. About 10% of an oral dose is excreted unchanged in the urine, the remainder being excreted in the faeces.