

Bergamot Oil

Bergamot Essence; Bergamota, aceite esencial de; Oleum Bergamottae.

Pharmacopoeias. In *Fr.* and *It.*

Profile

Bergamot oil is a greenish or brownish-yellow volatile oil with a characteristic fragrant odour and a bitter aromatic taste, obtained by expression from the fresh peel of fruit of *Citrus bergamia* (Rutaceae). Constituents include linalyl acetate and 5-methoxypsoralen (p.1607) and photosensitivity reactions have occurred following the topical use of preparations containing bergamot oil.

Bergamot oil is used in perfumery and as a flavour in Earl Grey tea. It has been included in some preparations for upper respiratory-tract disorders and hyperhidrosis. It is also used in aromatherapy.

♦ Muscle cramps have been reported¹ in a patient who drank up to 4 litres of 'Earl Grey' tea daily.

1. Finsterer J. Earl Grey tea intoxication. *Lancet* 2002; **359**: 1484.

Preparations

Proprietary Preparations (details are given in Part 3)

Multi-ingredient: *Fr.*: Ephydrol; *Ital.*: Bergacid; *Philipp.*: Kamillosan M; *Switz.*: Perskindol Classic.

Betahistine (BAN, rINN)

Betahistini; Betahistin; Betahistina; Bétahistine; Betahistinum. *N*-Methyl-2-(2-pyridyl)ethylamine.

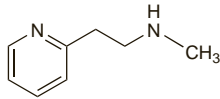
Бетагистин

$C_8H_{12}N_2 = 136.2$.

CAS — 5638-76-6.

ATC — N07CA01.

ATC Vet — QN07CA01.



Betahistine Hydrochloride (USAN, rINN)

Betahistini dihydrokloridi; Betahistin Dihydroklorür; Betahistin-dihydrochlorid; Betahistindihydroklorid; Bétahistine, Chlorhydrate de; Bétahistine, dichlorhydrate de; Betahistine Dihydrochloride (BANM); Betahistini dihydrochloridum; Betahistini Dihydrochloridum; Betahistino dihydrochloridas; Hidrocloruro de betahistina; PT-9. *N*-Methyl-2-(2-pyridyl)ethylamine dihydrochloride.

Бетагистина Гидрохлорид

$C_8H_{12}N_2 \cdot 2HCl = 209.1$.

CAS — 5579-84-0.

ATC — N07CA01.

ATC Vet — QN07CA01.

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

Ph. Eur. 6.2 (Betahistine Dihydrochloride). A white to slightly yellow, very hygroscopic, powder. Very soluble in water; soluble in alcohol; practically insoluble in isopropyl alcohol. A 10% solution in water has a pH of 2.0 to 3.0. Store in airtight containers.

USP 31 (Betahistine Hydrochloride). A white to almost yellow, very hygroscopic, crystalline powder. Very soluble in water; freely soluble in alcohol; practically insoluble in isopropyl alcohol. pH of a 10% solution in water is between 2.0 and 3.0.

Betahistine Mesilate (BANM, rINN)

Betahistini mesilaatti; Betahistin-dimesylát; Bétahistine, mésilate de; Betahistine Mesylate; Betahistini Dimesilas; Betahistini mesilas; Betahistinmesilat; Betahistino mesilasas; Betahisztin-mezilát; Mesilato de betahistina. *N*-Methyl-2-(2-pyridyl)ethylamine bismethanesulphonate.

Бетагистина Мезилат

$C_8H_{12}N_2 \cdot (CH_4O_3S)_2 = 328.4$.

CAS — 54565-23-4.

ATC — N07CA01.

ATC Vet — QN07CA01.

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

Ph. Eur. 6.2 (Betahistine Mesilate). A white or almost white, crystalline, very hygroscopic powder. Very soluble in water; freely soluble in alcohol; very slightly soluble in isopropyl alcohol. A 10% solution in water has a pH of 2.0 to 3.0. Store in airtight containers.

Adverse Effects

Gastrointestinal disturbances, headache, skin rashes, and pruritus have been reported.

Precautions

Betahistine should not be given to patients with phaeochromocytoma. It should be given with care to patients with asthma, peptic ulcer disease, or a history of peptic ulcer disease.

The symbol † denotes a preparation no longer actively marketed

Porphyria. Betahistine hydrochloride is considered to be unsafe in patients with porphyria because it has been shown to be porphyrinogenic in *in-vitro* systems.

Uses and Administration

Betahistine is an analogue of histamine and is claimed to improve the microcirculation of the labyrinth resulting in reduced endolymphatic pressure. It is used to reduce the symptoms of vertigo (p.565), tinnitus (p.1866), and hearing loss associated with Ménière's disease (p.564).

Betahistine is given orally as the hydrochloride or mesilate. The usual initial dose (of the hydrochloride) is 16 mg three times daily taken preferably with meals; maintenance doses are generally in the range of 24 to 48 mg daily. Betahistine mesilate is used in similar doses.

Reviews

1. Lacour M, Sterkers O. Histamine and betahistine in the treatment of vertigo: elucidation of mechanisms of action. *CNS Drugs* 2001; **15**: 853–70.

2. James AL, Burton MJ. Betahistine for Ménière's disease or syndrome. Available in The Cochrane Database of Systematic Reviews; Issue 1. Chichester: John Wiley; 2001 (accessed 30/05/06).

Preparations

BP 2008: Betahistine Dihydrochloride Tablets.

Proprietary Preparations (details are given in Part 3)

Arg.: Meniex; Microser; Ronistina; Travelmin; **Austral.:** Serc; **Austria:** Betaser; **Belg.:** Betahistop; Betaser; Docbetahi; **Braz.:** Betaser; Labinin; **Canad.:** Serc; **Chile:** Microser; **Cz.:** Avertin; Betaser; Microser; Polvertic; Zenostig; **Denm.:** Betaser; **Fin.:** Betaser; **Fr.:** Betaser; Evolis; Extovyt; Lectil; Serc; **Ger.:** Aequamen; Betaver; Melopat; Vasomotal; **Gr.:** Antivom; Betaser; Katabexin; Ribrain; Riva; **Hong Kong:** Beta-Synto; Betaser; Bymeniere; Meniero; Merislon; **Hung.:** Betagen; Betaser; Elven; Microser; **India:** Betahist; Vertin; **Indon.:** Betaser; Merislon; Mertigo; Noverty; Vastigo; Vercure; Versilon; Vertex; **Irl.:** By-Vertin; Serc; Vertigon; **Israel:** Agiser; Betistine; **Ital.:** Microser; Sincrover; Vertiser; **Jpn:** Merislon; **Malaysia:** Alfinor; Betaser; Merislon; **Mex.:** Serc; **Neth.:** Betaser; **NZ:** Serc; Vergo; **Philipp.:** Merislon; Serc; Vertilate; **Pol.:** Betaser; Histimer; Microser; **Port.:** Betaser; Merislon; **Rus.:** Betaser (Betacepi); Vestibo (Вестибо); **S.Afr.:** Serc; **Singapore:** Betaser; Merislon; **Spain:** Fidium; Serc; **Switz.:** Betaser; **Thai.:** Behistin; Betahist-B; Merislon; Merlin; Serc; **Turk.:** Betaser; Vasoser; **UK:** Serc; **Venez.:** Microser; Serc.

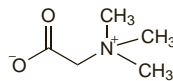
Betaine

Betaina; Glycine Betaine; Glycocol Betaine; Lcine; Trimethylglycine. (Carboxymethyl)trimethylammonium hydroxide inner salt. $C_5H_{11}NO_2 = 117.1$.

CAS — 107-43-7.

ATC — A16AA06.

ATC Vet — QA16AA06.



Betaine Hydrochloride

Betainihydrokloridi; Betaina, hidrocloruro de; Betainhydroklorid; Betaini Hydrochloridum; Trimethylglycine Hydrochloride. (Carboxymethyl)trimethylammonium hydroxide inner salt hydrochloride.

$C_5H_{11}NO_2 \cdot HCl = 153.6$.

CAS — 590-46-5.

ATC — A09AB02.

ATC Vet — QA09AB02.

Pharmacopoeias. In *US*.

USP 31 (Betaine Hydrochloride). A white crystalline powder. Soluble in water and in alcohol; practically insoluble in chloroform and in ether. A 25% solution in water has a pH of 0.8 to 1.2.

Profile

Betaine is used as a methyl donor to remethylate homocysteine to methionine in the treatment of patients with homocystinuria (see Amino Acid Metabolic Disorders, p.1922). It is given orally in a usual dose of 3 g twice daily. Doses are adjusted according to plasma-homocysteine concentrations; up to 20 g daily has been required in some patients. In children under 3 years old, an initial dose of 100 mg/kg daily given in 2 divided doses may be used.

Severe cerebral oedema and hypermethioninaemia have been reported in a few patients, and it is recommended that plasma-methionine concentrations should be monitored at the start of betaine treatment and periodically thereafter. Patients being treated for cystathionine beta-synthase deficiency may pose particular problems because betaine may further raise their already elevated methionine concentrations increasing the risk of cerebral oedema.

Betaine has also been used as a variety of salts in preparations for liver and gastrointestinal disorders. The hydrochloride has been given as a source of hydrochloric acid in the treatment of hypochlorhydria.

Adverse effects. References.

1. Devlin AM, *et al.* Cerebral edema associated with betaine treatment in classical homocystinuria. *J Pediatr* 2004; **144**: 545–8.

Homocystinuria. References.

- Smolin LA, *et al.* The use of betaine for the treatment of homocystinuria. *J Pediatr* 1981; **99**: 467–72.
- Wilcken DEL, *et al.* Homocystinuria—the effects of betaine in the treatment of patients not responsive to pyridoxine. *N Engl J Med* 1983; **309**: 448–53.
- Holme E, *et al.* Betaine for treatment of homocystinuria caused by methylenetetrahydrofolate reductase deficiency. *Arch Dis Child* 1989; **64**: 1061–4.
- Anonymous. Betaine for homocystinuria. *Med Lett Drugs Ther* 1997; **39**: 12.

Liver disorders. Betaine has also been investigated for the treatment of nonalcoholic steatohepatitis.

References.

- Miglio F, *et al.* Efficacy and safety of oral betaine glucuronate in non-alcoholic steatohepatitis: a double-blind, randomized, parallel-group, placebo-controlled prospective clinical study. *Arzneimittelforschung* 2000; **50**: 722–7.
- Abdelmalek MF, *et al.* Betaine, a promising new agent for patients with nonalcoholic steatohepatitis: results of a pilot study. *Am J Gastroenterol* 2001; **96**: 2711–7.

Pharmacokinetics. References.

- Schwahn BC, *et al.* Pharmacokinetics of oral betaine in healthy subjects and patients with homocystinuria. *Br J Clin Pharmacol* 2003; **55**: 6–13.

Preparations

Proprietary Preparations (details are given in Part 3)

Austral.: Cystadane; **Canad.:** Cystadane; **Cz.:** Cystadane; **Israel:** Cystadan; **Ital.:** Somaty; **Port.:** Cystadane; **USA:** Cystadane.

Multi-ingredient: **Arg.:** Eucos-L; **Austral.:** Betaine Digestive Aid; Bioglan Digestive Zyme; Digestaid; **Austria:** CO Granulat; Oroacid; **Belg.:** Digestomen; **Braz.:** Aminotox; Anekron; Betalver; Biohexac; Colachofra; Enterofigon; Epocler; Hepacitron; Hepalin; Hepatobef; Hepatox; Hormo Hepatico; Meticolin Composto; Necro B-6; Xantinox Complex; **Cz.:** Citrargine; CO Granulat; **Fr.:** Citrargine; Gastrobul; Hepagrum; Nivabetol; Ornitate; **Ger.:** CO Granulat; Flacar; Unexym MD S; **Gr.:** Klorof; **Hong Kong:** Jeteap; **Hung.:** Betacid; Gastrobul; **Indon.:** Naturica DFM; **Israel:** Betazim; **Ital.:** Citroepatina; Epabetina; Jeteap; **Malaysia:** Jeteap; **Neth.:** Serc; **Philipp.:** Jeteap; **S.Afr.:** Klorof; **Singapore:** Jeteap; **Switz.:** Pepsi-Chlor; **UK:** Enzyme Digest; Enzyme Plus; Klorof.

Bethanechol Chloride (BAN)

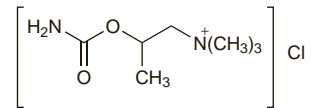
Betanecol, cloruro de; Betanekolklorid; Betanekolklorid; Bethanecholi Chloridum; Carbamylmethylcholine Chloride. (2-Carbamoyloxypropyl)trimethylammonium chloride.

$C_7H_{17}ClN_2O_2 = 196.7$.

CAS — 674-38-4 (bethanechol); 590-63-6 (bethanechol chloride).

ATC — N07AB02.

ATC Vet — QN07AB02.



Pharmacopoeias. In *Jpn* and *US*.

USP 31 (Bethanechol Chloride). Colourless or white crystals, or white crystalline powder, usually having a slight, amine-like odour. It is hygroscopic and exhibits polymorphism. Freely soluble in water and in alcohol; insoluble in chloroform and in ether. pH of a 1% solution in water is between 5.5 and 6.5. Store in airtight containers.

Stability. References to the stability of oral liquid preparations of bethanechol chloride prepared extemporaneously from tablets.

- Schlatter JL, Saulnier J-L. Bethanechol chloride oral solutions: stability and use in infants. *Ann Pharmacother* 1997; **31**: 294–6.
- Allen LV, Erickson MA. Stability of bethanechol chloride, pyrazinamide, quinidine sulfate, rifampin, and tetracycline hydrochloride in extemporaneously compounded oral liquids. *Am J Health-Syst Pharm* 1998; **55**: 1804–9.

Sterilisation. The US manufacturers state that solutions of bethanechol chloride may be autoclaved at 120° for 20 minutes without discoloration or loss of potency.

Adverse Effects and Treatment

As described for choline esters under Acetylcholine Chloride, p.1877.

Precautions

As described for choline esters under Acetylcholine Chloride, p.1877.

Bethanechol should not be given by the intravenous or intramuscular routes as very severe muscarinic adverse effects are liable to occur, calling for emergency use of atropine.

Autonomic neuropathy. Patients with autonomic neuropathy might be more susceptible to the adverse effects of bethanechol and they should be started on low-dosage regimens and observed closely for signs of toxicity.¹

1. Caraco Y, *et al.* Bethanechol-induced cholinergic toxicity in diabetic neuropathy. *DICP Ann Pharmacother* 1990; **24**: 327–8.

Interactions

As for Neostigmine, p.632.

Pharmacokinetics

Bethanechol chloride is poorly absorbed from the gastrointestinal tract. It is not hydrolysed by cholinesterases. At standard doses bethanechol does not cross the blood-brain barrier.

Uses and Administration

Bethanechol chloride, a choline ester, is a quaternary ammonium parasympathomimetic that mainly exhibits the muscarinic actions of acetylcholine (p.1877). It is not inactivated by cholinesterases so its actions are more prolonged than those of acetylcholine. Bethanechol chloride has little if any nicotinic activity and is used for its actions on the bladder and gastrointestinal tract. It has been used as an alternative to catheterisation in the treatment of urinary retention and has also been used for gastric atony and retention, abdominal distension following surgery, congenital megacolon, and gastro-oesophageal reflux disease.

Bethanechol chloride is given in usual doses of 5.15 mg subcutaneously or 10 to 50 mg orally, both up to 4 times daily, but dosage must be adjusted individually. Oral doses should be taken on an empty stomach. The effects usually occur within 5 to 15 minutes of a subcutaneous dose, or 30 to 90 minutes of an oral dose, and disappear within about 1 to 2 hours depending on the dose and route. However, large oral doses (300 to 400 mg) may produce effects for up to 6 hours. For a warning to avoid intravenous or intramuscular use, see under Precautions, above.

Decreased gastrointestinal motility. Parasympathomimetics such as bethanechol enhance gastric contractions and increase intestinal motility and form just one of many treatments that have been used in conditions associated with decreased gastrointestinal motility (p.1694).

Gastro-oesophageal reflux disease. Prokinetic drugs such as bethanechol have been tried in gastro-oesophageal reflux disease (p.1696).

References.

1. Thanick KD, *et al.* Reflux esophagitis: effect of oral bethanechol on symptoms and endoscopic findings. *Ann Intern Med* 1980; **93**: 805–8.
2. Saco LS, *et al.* Double-blind controlled trial of bethanechol and antacid versus placebo and antacid in the treatment of erosive esophagitis. *Gastroenterology* 1982; **82**: 1369–73.
3. Thanick K, *et al.* Bethanechol or cimetidine in the treatment of symptomatic reflux esophagitis: a double-blind control study. *Arch Intern Med* 1982; **142**: 1479–81.
4. Strickland AD, Chang JHT. Results of treatment of gastro-oesophageal reflux with bethanechol. *J Pediatr* 1983; **103**: 311–15.

Stuttering. A double-blind placebo-controlled study¹ in 10 patients with stuttering (p.1001) on the whole failed to confirm an earlier report² of benefit using bethanechol although 2 patients who did respond elected to continue treatment after the study.

1. Kampman K, Brady JP. Bethanechol in the treatment of stuttering. *J Clin Psychopharmacol* 1993; **13**: 284–5.
2. Hays P. Bethanechol chloride in treatment of stuttering. *Lancet* 1987; **i**: 271.

Urinary incontinence and retention. Bethanechol is one of the parasympathomimetics that have been given to increase detrusor activity in patients with overflow incontinence, but there have been doubts about the effectiveness of such treatment (see p.2180). Bethanechol was also one of the parasympathomimetics used in the management of postoperative urinary retention but they have generally been superseded by catheterisation.

References.

1. Finkbeiner AE. Is bethanechol chloride clinically effective in promoting bladder emptying: a literature review. *J Urol (Baltimore)* 1985; **134**: 443–9.
2. Kemp B, *et al.* Prophylaxis and treatment of bladder dysfunction after Wertheim-Meigs operation: the positive effect of early postoperative detrusor stimulation using the cholinergic drug bethanecholchloride. *Int Urogynecol J Pelvic Floor Dysfunct* 1997; **8**: 138–41.
3. Riedl CR, *et al.* Electromotive administration of intravesical bethanechol and the clinical impact on acontractile detrusor management: introduction of a new test. *J Urol (Baltimore)* 2000; **164**: 2108–11.

Preparations

USP 31: Bethanechol Chloride Injection; Bethanechol Chloride Oral Solution; Bethanechol Chloride Oral Suspension; Bethanechol Chloride Tablets.

Proprietary Preparations (details are given in Part 3)

Arg.: Miotonachol; **Austral.:** Urocarb; **Austria:** Myocholine; **Belg.:** Myocholine; **Braz.:** Liberan; **Canad.:** Duvoid; Myotonachol; **Ger.:** Myocholine; **India:** Urotone; Urotonine; **Israel:** Urocholine; **Switz.:** Myocholine; **Thai.:** Ucholine; Urocholine; **UK:** Myotonine; **USA:** Myotonachol; Urocholine.

Bibrocathol (*rINN*)

Bismocathin; Bibrocatholum; Bibrocato; Bibrokatol; Bibrokatoli; Bismuth Tetrabromopyrocatechinate; Tetrabromopyrocatechol Bismuth. 4,5,6,7-Tetrabromo-2-hydroxy-1,3,2-benzodioxabis-mole.

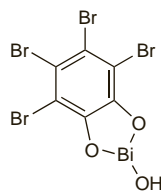
Биброкато́л

$C_6H_5Br_4O_3 = 649.7$.

CAS — 6915-57-7.

ATC — S01AX05.

ATC Vet — QS01AX05.

**Profile**

Bibrocathol is a bismuth-containing compound that has been applied topically in the treatment of eye disorders, wounds, and burns.

Preparations**Proprietary Preparations** (details are given in Part 3)

Ger.: Noviform; Posiformin; **Swed.:** Noviform; **Switz.:** Noviform†.

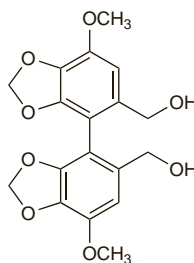
Multi-ingredient. Ger.: Novifort†.

Bicyclol

4,4'-Dimethoxy-5,6,5',6'-bis(methylene-dioxy)-2-hydroxymethyl-2'-methoxycarbonyl biphenyl.

Бицикло́л

$C_{19}H_{18}O_9 = 390.3$.

**Profile**

Bicyclol has been used as a hepatoprotectant in the management of hepatitis. It has been given orally in a dose of 25 or 50 mg three times daily for at least 6 months.

References.

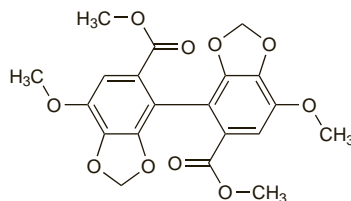
1. Liu Q, *et al.* A useful agent for chemoprevention of hepatocellular carcinoma? *Cancer Biol Ther* 2006; **5**: 1674–6.
2. Wu T, *et al.* Bicyclol for chronic hepatitis B. Available in The Cochrane Database of Systematic Reviews; Issue 4. Chichester: John Wiley; 2006 (accessed 01/05/08).
3. Yang XY, *et al.* Bicyclol for chronic hepatitis C. Available in The Cochrane Database of Systematic Reviews; Issue 1. Chichester: John Wiley; 2007 (accessed 01/05/08).

Bifendate

Dimethyl 7,7'-dimethoxy-(4,4'-bi-1,3-benzodioxole)-5,5'-dicarboxylate.

$C_{20}H_{18}O_{10} = 418.4$.

CAS — 73536-69-3.

**Pharmacopoeias.** In *Chin.***Profile**

Bifendate is derived from schisandra (see p.2384). It is used in Chinese medicine for chronic hepatitis.

Bifendate has been reported to reduce blood concentrations of ciclosporin (see p.1826).

Bile Acids and Salts

Biliares, ácidos y sales.

CAS — 81-25-4 (cholic acid); 11006-55-6 (sodium tauroglycocholate); 361-09-1 (sodium cholate).

Pharmacopoeias. *Jpn* includes bear bile.

Profile

The principal primary bile acids, cholic acid and chenodeoxycholic acid (p.2280), are produced in the liver from cholesterol and are conjugated with glycine or taurine to give glycocholic acid, taurocholic acid, glycochenodeoxycholic acid, and taurochenodeoxycholic acid, before being secreted into the bile where they are present as the sodium or potassium salts (bile salts). Secondary bile acids are formed in the colon by bacterial deconjugation and 7 α -dehydroxylation of cholic acid and chenodeoxycholic acid, producing deoxycholic acid and lithocholic acid, respectively. Ursodeoxycholic acid (p.2408) is a minor bile acid in man although it is the principal bile acid in *bears*. Dehydrocholic acid (p.2292) is a semisynthetic bile acid.

The total body pool of bile salts is about 3 g, and most of the secreted bile salts are reabsorbed in a process of enterohepatic recycling, so that only a small fraction of this amount must be synthesised *de novo* each day.

Bile salts are strongly amphiphilic; with the aid of phospholipids they form micelles and emulsify cholesterol and other lipids in bile. Oral administration of chenodeoxycholic acid also reduces the synthesis of cholesterol in the liver, while ursodeoxycholic acid reduces biliary cholesterol secretion apparently by increasing conversion of cholesterol to other bile acids. The bile acids (but not the bile salts) also have a choleric action, increasing the secretion of bile, when given by mouth.

Chenodeoxycholic acid and ursodeoxycholic acid are given by mouth in the management of cholesterol-rich gallstones (p.2409) in patients unsuited to, or unwilling to undergo, surgery. Ursodeoxycholic acid is also being studied in some liver disorders.

Preparations containing bile salts have been used to assist the emulsification of fats and absorption of fat-soluble vitamins in conditions in which there is a deficiency of bile in the gastrointestinal tract. Ox bile has also been used in the treatment of chronic constipation. Cholic acid is used for the treatment of inborn errors in primary bile synthesis.

Sodium cholate has been used for its spermicidal properties in barrier contraceptives.

Preparations**Proprietary Preparations** (details are given in Part 3)

Chile: Desicol; **Ger.:** Cholecysmon†; **Mex.:** Virulizin; **Rus.:** Festal (Dectra); **S.Afr.:** Bilron†; **Venez.:** Hepa-Desicol.

Multi-ingredient. Arg.: Bibol Leloup; Bil 13; Bilagol; Bilidren; Bilosan Compuesto†; Carbogasol Digestivo; Cascara Sagrada Bouzen†; Digesplen; Gastron Fuerte†; Hepatolagina; Nilflux; Opobyl; Pankreon Compuesto†; Veracolate; Zimerol; **Austral.:** Digestaid; Enzyme; Lexat†; **Austria:** Arca-Enzyme; Buccalin; **Belg.:** Buccaline; Grains de Vals; **Braz.:** B-Vesil; Dasc; Emagrex†; Figatil; Jurubleno†; Nutrizim†; **Canad.:** Bicholate; Herbalax†; Laxative†; Protectaid; **Chile:** Combizym Compositum; Combizym†; Flapex E; Hepabil; K.C.M.C; Katin; Onotont†; **Cz.:** Combizym Compositum; **Fin.:** Combizym Compositum; **Fr.:** Rectopaniline; **Ger.:** Combizym Compositum†; **Hong Kong:** Bilisan; Buccaline†; Enzyme; Hepatofalk; Protectaid; Topaset†; **Hung.:** Combizym Compositum†; **India:** Digelex-T; Dispeptal†; Farizym; Ipeptal†; Merckenzym; Panolaset†; Papytazyme; **Indon.:** Benozym; Berzymplex; Cotazym Forte; Enzymfort; Enzyme; Eviprost†; Pankreon Comp; **Israel:** Encypalmel; **Ital.:** Solvobil; **Malaysia:** Enzyme; **Mex.:** Dirfaben†; Dixifen; Espaven Enzimatico; Ochozoin; Onotont; Zimeton; **NZ:** Buccaline; **Port.:** Byli†; Caroid†; Combizym Compositum†; Fermetone Composto; **Rus.:** Ipeptal (Ipeptat); **Singapore:** Enzyme; **Spain:** Menabil Complex†; **Swed.:** Combizym Compositum; **Switz.:** Buccaline; Combizym Compositum; **Thai.:** Buccaline†; Combizym Compositum; Enzyme; Papytazyme†; Veracolate; **Turk.:** Flaton; Intestinal; Multanzim; Pankrodigest; **UK:** Protectaid; **USA:** Digepepsin; **Venez.:** Combizym Forte; Nutizym Compositum; Pankreon Compositum; Stamy†.

Birch Leaf

Abedul, hojas de; Beržų lapai; Betulae folium; Birkenblätter; Björkblad; Bouleau; Bouleau, feuille de; Březový list; Koivunlehti; Lišč brzozy; Njyřaleví; Silver Birch Leaf.

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

Ph. Eur. 6.2 (Birch Leaf). The whole or fragmented dried leaves of *Betula pendula* and/or *B. pubescens* as well as hybrids of both species. It contains not less than 1.5% of flavonoids, calculated as hyperoside ($C_{21}H_{20}O_{12} = 464.4$), with reference to the dried drug. Protect from light.

Profile

Birch leaf is used in herbal medicine, particularly for urinary tract disorders. Birch leaf oil has also been used.

Preparations**Proprietary Preparations** (details are given in Part 3)

Ger.: Urorenal†.

Multi-ingredient. Arg.: Sequals G; **Austral.:** Guaiacum Complex†; **Austria:** Blasente St Severin; Heumann's Blasen- und Nierentee; Rheuma; Solubrat; **Cz.:** Abführ-Heilkräutertee†; Blasen- und Nierentee†; Cajova Smes pri Redukcni Diete†; Fytokliman Planta; Nephrosal†; Reduktan; Senalac; Species Diureticae Planta†; Species Urologicae Planta; Stoffwechseltee N†; Urologicka Cajova Smes; **Fr.:** B.O.P; Depuratum; Drainactil; Mediflor no 11 Draineur Renal et Digestif; Mediflor Tisane Antirhumatismale No 2; **Ger.:** Anthypertonicum S; BioCyst; Canephron novot†; Cystinol N; Dr Wiemanns Rheumatikum; Dr Scheffler Bergischer Kräutertee Blasen- und Nierentee; Hamtee 400 N; Hamtee STADA; Hamtee-Steiner; Heumann Blasen- und Nierentee Solubrat S†; Heumann Blasen- und Nierentee Solubrat uro; Hamtee-Blasen-Nieren-Tee N; Hweberberol-Tee; Nephropasc†; Nephronorm med†; Nephropur tri†; Nephroselect M; Nephrobrin-N†; Nierentee 2000†; Nieren-Blasen- und Nieren-Tee V†; Nieren-Tee N†; Presselin Nieren-Blasen K 3†; Renob Blasen- und Nierentee; Urodi phyto†; **Ital.:** Betulla (Specie Composita)†; Gramigna (Specie Composita)†; Lipaven; Listerine Fresh Citrus; Listerine Tartar Control; **Pol.:** Betasol; Diabetofort; Herbaton; Nefrobonis; NeoFitolizyn; Urosept; **Rus.:** Herbon Urological