

- Hooper L, et al. Risks and benefits of omega 3 fats for mortality, cardiovascular disease, and cancer: systematic review. *BMJ* 2006; **332**: 752–60.
- Jatoi A, et al. An eicosapentaenoic acid supplement versus megesterol acetate versus both for patients with cancer-associated wasting: a North Central Cancer Treatment Group and National Cancer Institute of Canada collaborative effort. *J Clin Oncol* 2004; **22**: 2469–76.
- Dewey A, et al. Eicosapentaenoic acid (EPA, an omega-3 fatty acid from fish oils) for the treatment of cancer cachexia. Available in The Cochrane Database of Systematic Reviews; Issue 1. Chichester: John Wiley; 2007 (accessed 30/05/08).

Neurological and psychiatric disorders. Omega-3 fatty acids concentrate in neuronal membranes and appear to have an important role in brain development and function. Supplementation during pregnancy and in infants has been investigated, but there is little evidence that maternal supplements improve neonatal outcomes,¹ and only limited evidence of a benefit on growth and neurodevelopment in preterm infants given milk formulas supplemented with both omega-3 and omega-6 fatty acids.^{2,3} However, in older children with phenylketonuria treated with dietary restriction, omega-3 fatty acid supplements may improve motor skills.⁴

Omega-3 fatty acids have also been tried in the treatment of neurological and psychiatric disorders.^{5,6} There appears to be a link between deficient fatty acid intake and mood disorders,⁷ and there is reasonable evidence to support the use of omega-3 fatty acids as adjuncts in the treatment of depression, including possible benefit in the depressive symptoms of bipolar disorder, but further studies are needed to confirm this.^{8–10} Benefit has been shown in schizophrenia, but results have been mixed and the role of omega-3 fatty acids is not established.¹¹ Some positive results have been reported in hyperactivity and in autism, but further studies are needed.¹² Omega-3 fatty acids have also been tried in dementia, but there is not yet sufficient evidence¹³ to recommend them for prevention.

Eicosapentaenoic acid ethyl ester has been tried in Huntington's disease, and may improve motor function,¹⁴ but this remains to be confirmed.

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- Fewtrell MS, et al. Randomized, double-blind trial of long-chain polyunsaturated fatty acid supplementation with fish oil and borage oil in preterm infants. *J Pediatr* 2004; **144**: 471–9.
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- Parker G, et al. Omega-3 fatty acids and mood disorders. *Am J Psychiatry* 2006; **163**: 969–78.
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- Joy CB, et al. Polyunsaturated fatty acid supplementation for schizophrenia. Available in The Cochrane Database of Systematic Reviews; Issue 3. Chichester: John Wiley; 2006 (accessed 30/05/08).
- Richardson AJ. Omega-3 fatty acids in ADHD and related neurodevelopmental disorders. *Int Rev Psychiatry* 2006; **18**: 155–72.
- Lim WS, et al. Omega-3 fatty acid for the prevention of dementia. Available in The Cochrane Database of Systematic Reviews; Issue 1. Chichester: John Wiley; 2006 (accessed 30/05/08).
- Puri BK, et al. Ethyl-EPA in Huntington disease: a double-blind, randomized, placebo-controlled trial. *Neurology* 2005; **65**: 286–92.

Preparations

USP 31: Fish Oil containing Omega-3 Acids Capsules.

Proprietary Preparations (details are given in Part 3)

Arg: Regulip; **Austral:** Bioglan Maxepe; Fishaphos; Maxepe†; **Austria:** Eicosapen; Omacor; Omegaven; **Belg:** Omacor; **Braz:** Votag; **Canada:** Focus 425; **Chile:** Epasan Omega 3; Eykosacol; Neuromin†; Omegaven; Sanepa Forte†; **Cz:** Omacor; Omegaven; **Denm:** Omegaven; **Fr:** Epabiol; Maxepe; OM3; Omacor; Omega 3; Omega 3†; Omegaven; Psoriacalm; Triglistab; **Ger:** Ameu; Eicosan; Eicosapen; Lipicor; Omacor; Omegaven; Zodin; **Gr:** Farlipid; Maxepe; Omacor; Zodin; **Hong Kong:** Lipomega; Smartfish; **Hung:** Omacor; Omegaven; **India:** Maxepe; **Indon:** Champs DHA; Proclacta with DHA; Proclacta with DHA for Mother; **It:** Maxepe; Omacor; **Israel:** Omegaven; **Ital:** Almic; Esapent; Eskim; Fish Factor; Maxepe; Omegaven; Seacor; Triolip; Triomar; **Jpn:** Epadel; **Malaysia:** Champs DHA; Hovid Omega-3†; Mlepa; Quest Gamma EPA Plus; VitaEPA†; **Mex:** Colega-3; Fresomega; **Neth:** Omacor; Omegaven; Zodin; **Norw:** Omacor; **Philipp:** Fisot; Omacor; Zymechol; **Pol:** BioCardine; Galomega†; Omega-3; Omegaven; Trienyl; **Port:** Omacor; Omegaven; Zodin; **Rus:** Omacor (Омакор); **Singapore:** Champs DHA; **Spain:** Omacor; **Swed:** Omegaven; **Switz:** Ameu†; Eicosapen; Epacaps; Omega-3; Omegaven; **Thai:** Omacor; **Turk:** Marincap; Omega III; Omegaven; **UK:** Maxepe; Omacor; Pure Omega; **USA:** Cardi-Omega 3; Cholestin; Lovasa; Lovaza; Maxepe; Promega; SuperEPA; **Venez:** Epax; Fizoll; Marina; Maxepe; Ometrix.

Multi-ingredient: **Arg:** Cholesterol Reducing Plan†; **Austral:** APR Cream†; Arthriforte; Bioglan Arthri Plus; Bioglan Zellulean with Escin; Curaderm†; Efalex†; Efamarine†; ER Cream†; Himegast; LifeChange Circulation

Aid†; Macro Maxepe†; Maxepe & EPO†; Naudicelle Marine†; Pre Natal†; Vita-Preg†; **Austria:** SMOFlipid; **Braz:** Borag; Glavit; Lipcor†; Lisacol†; **Canada:** Bionagre plus E; Efalex†; **Chile:** Acnoxyf Jabon†; Celtech Gold; **Cz:** Lipoplus; SMOFlipid; **Denm:** SMOFlipid; **Fin:** Lipoplus; **Fr:** A-Flam; Arthrolib; Bio-Marine Plus†; Bionagrol Plus; Cardiom3; Dioptec; Efadiane relipidantes; Elteans; Molva; OM3 Junior; Omegacoer; Phytophanere; Reti-Nat; Synerbiol; **Ger:** SMOFlipid; **Gr:** Atrol; Dynapen-3; Emfrastop; Epadoc; Lipemia; Pazeril; Prolipid; Salmon Oil; SMOFlipid; **Hong Kong:** Biomega-3†; Doctor's Choice Omega 3; Eye Q; Himegast; Mumomega; **Hung:** SMOFlipid; **India:** Cadvion; Dicloran MS; Megasoft-E; **Indon:** Co-Q-10; Flexasur; Maxtrin; Nulacta Li; Obipluz; Prenatin-DF; Vitazym; **It:** MorD-HA; MorEPA; **Israel:** Triomar; **Ital:** Agedin Plus; Derman-Oil; Dermana Crema; Dermana Pasta; DHA; Ditrevit; Fitogenase; Fotrec DHA; Gamma-plus; Ictom 3†; Memoactive†; Secri; Trofinerv; Trofinerv Antiox; Venactive†; Venoton; **Malaysia:** Adult Citrex Multivitamin + Ginseng + Omega 3; VitaEPA Plus†; **Neth:** Lipoplus; SMOFlipid; **Norw:** SMOFlipid; **NZ:** Efaclat; Efalex; Efamarine; Efamax; **Philipp:** Memori Plus; OB Smart SG; **Pol:** SMOFlipid; **Port:** Lipoplus; **Singapore:** CardioCare; Celatrac; Gissicor; Seven Seas JointCare; Seven Seas JointCare High Strength; Seven Seas Joint-Care Max; VitaEPA; VitaEPA Plus; **Swed:** Lipoplus; SMOFlipid; **Switz:** Vitafissan N; **UK:** Chol-Aid; Efalex; Efamarine; GlucOsamax; Lipidem; Omegaven; Pregnacare Plus; ProBrain; SMOFlipid; **USA:** Animi-3; Citracal Prenatal + DHA; Duet DHA; Marine Lipid Concentrate; Optinate Omega-3; Sea-Omega; **Venez:** Eidoca; Piscis 3.

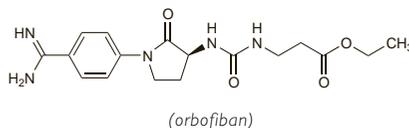
Orbofiban Acetate (USAN, rINNM)

Acetato de orbofibrán; CS-511; Orbofiban, Acétate d'; Orbofiban Acetate; SC-57099-B. N-[[[(3S)-1-(p-Amidinophenyl)-2-oxo-3-pyrrolidiny]carbonyl]-β-alanine ethyl ester monoacetate quadrant hydrate.

Орбофибана Ацетат

C₁₇H₂₃N₅O₄·C₂H₄O₂·H₂O = 426.0.

CAS — 163250-90-6 (orbofiban); 165800-05-5 (orbofiban acetate).



Profile

Orbofiban is a glycoprotein IIb/IIIa-receptor antagonist. It has been investigated as an oral antiplatelet drug in unstable angina and myocardial infarction but has been associated with an increase in mortality.

References

- Cannon CP, et al. Oral glycoprotein IIb/IIIa inhibition with orbofiban in patients with unstable coronary syndromes (OPUS-TIMI 16) trial. *Circulation* 2000; **102**: 149–56.

Ouabain

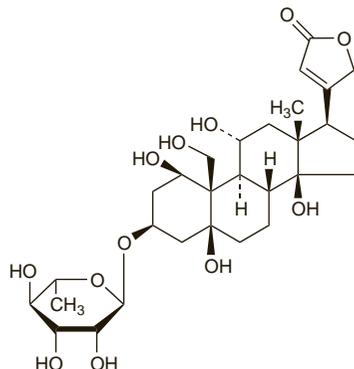
Acocantherin; G-Strophanthin; Ouabaini; Ouabain oktahydrát; Ouabaina; Ouabainas; Ouabaine; Ouabainum; Ouabainum Octahydricum; Strophanthin-G; Strophanthinum; Strophanthoside-G; Uabaina; Uabaina. 3β-(α-L-Rhamnopyranosyloxy)-1β,5,11α-,14,19-pentahydroxy-5β,14β-card-20(22)-enolide octahydrate.

C₂₉H₄₄O₁₂·8H₂O = 728.8.

CAS — 630-60-4 (anhydrous ouabain); 11018-89-6 (ouabain octahydrate).

ATC — C01AC01.

ATC Vet — QC01AC01.



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

Ph. Eur. 6.2 (Ouabain). Colourless crystals or white or almost white, crystalline powder. Sparingly soluble in water and in dehydrated alcohol; practically insoluble in ethyl acetate. Protect from light.

Profile

Ouabain is a cardiac glycoside with positive inotropic activity that is obtained from the seeds of *Strophanthus gratus* or from the wood of *Aconitum napellus* or *A. ouabaio* (Apocynaceae). It has general properties similar to those of digoxin (p.1259) and may be used in the treatment of heart failure (p.1165). Ouabain is given orally in a dose of up to 24 mg daily; it has also been given intravenously.

Preparations

Proprietary Preparations (details are given in Part 3)

Ger: Strodival.

Oxedrine (BAN) ⓧ

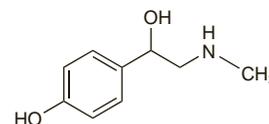
Oksedriini; Oxedrin; Oxedrinum; Sinefrina; Sympaethaminum; Synephrine; p-Synephrine. (R_S)-1-(4-Hydroxyphenyl)-2-(methylamino)ethanol.

C₉H₁₃NO₂ = 167.2.

CAS — 94-07-5.

ATC — C01CA08; S01GA06.

ATC Vet — QC01CA08; Q501FB90; Q501GA06.



NOTE. Synephrine and p-synephrine have been used as synonyms for oxedrine. Care should be taken to avoid confusion with m-synephrine, which is phenylephrine (p.1568).

Oxedrine Hydrochloride (BANM) ⓧ

Sinefrina, hidrocloruro de.

C₉H₁₃NO₂·HCl = 203.7.

ATC — C01CA08; S01GA06.

ATC Vet — QC01CA08; Q501GA06.

Oxedrine Tartrate (BANM) ⓧ

Aetaphen. Tartrat; Aethaphenum Tartaricum; Oksedriintartraatti; Oxedriini Tartras; Oxedrintartrat; Oxyphenylmethylaminoethanol Tartrate; Sinefrina Tartrato; Sinefrina, tartrato de; Synephrine Tartrate.

(C₉H₁₃NO₂)₂·C₄H₆O₆ = 484.5.

CAS — 16589-24-5 (oxedrine tartrate); 67-04-9 (±oxedrine tartrate).

ATC — C01CA08; S01GA06.

ATC Vet — QC01CA08; Q501GA06.

Profile

Oxedrine is a sympathomimetic (p.1407) given as the tartrate in the treatment of hypotensive states in oral doses of about 100 to 150 mg three times daily; it has also been given by subcutaneous, intramuscular, or intravenous injection.

Oxedrine is also used in eye drops as an ocular decongestant, usually as the tartrate in a concentration of 0.5% in combination preparations. The hydrochloride has also been used.

Preparations

Proprietary Preparations (details are given in Part 3)

Austria: Sympatol; **Hong Kong:** Ocuton; **Hung:** Sympathomim; **Ital:** Sympatol; **Switz:** Sympalept.

Multi-ingredient: **Austria:** Dacrin; Pasuma-Dragees; **Fr:** Dacryne; Dacryboraline; Polyfira; Posinet†; Sedacollyre; Uvicol.

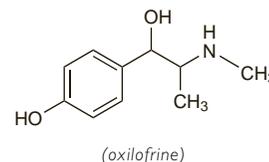
Oxilofrine Hydrochloride (rINNM) ⓧ

Hidrocloruro de oxilofrina; p-Hydroxyephedrine Hydrochloride; Methylsynephrine Hydrochloride; Oxilofrine, Chlorhydrate d'; Oxilofrini Hydrochloridum; Oxyphephrine Hydrochloride. erythro-p-Hydroxy-α-[1-(methylamino)ethyl]benzyl alcohol hydrochloride.

Оксиллофрина Гидрохлорид

C₁₀H₁₅NO₂·HCl = 217.7.

CAS — 942-51-8.



Profile

Oxlofrine is a sympathomimetic (p.1407) related to ephedrine (p.1558). It is given orally as the hydrochloride in the treatment of hypotensive states in usual doses of 16 mg three times daily, although higher doses have been given. It has also been used in antitussive preparations.

Preparations

Proprietary Preparations (details are given in Part 3)

Austria: Carnigen; **Ger.:** Carnigen.

Multi-ingredient: **Canad.:** Cophylac.

Oxprenolol Hydrochloride

(BANM, USAN, rINNM) ⊗

Ba-39089; Hidrocloruro de oxiprenolol; Hidrocloruro de oxprenolol; Oksprenolol Hidroklorür; Oksprenololhidroklorid; Oksprenololo hidrokloridas; Oksprenololu chlorowoderek; Oxprénolol, chlorhydrate d'; Oxprenolol hydrochlorid; Oxprenololhidroklorid; Oxprenololhydrochlorid; Oxprenololi hydrochloridum; Oxyprenolol Hydrochloride. 1-(*o*-Allyloxyphenoxy)-3-isopropylaminopropan-2-ol hydrochloride.

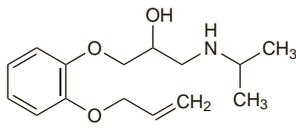
Оксспренолола Гидрохлорид

C₁₅H₂₃NO₃·HCl = 301.8.

CAS — 6452-71-7 (oxprenolol); 6452-73-9 (oxprenolol hydrochloride).

ATC — C07AA02.

ATC Vet — QC07AA02.



(oxprenolol)

NOTE. Compounded preparations of oxprenolol hydrochloride may be represented by the following names:

- Co-prenozide (BAN)—oxprenolol hydrochloride 640 parts and cyclopenthiiazide 1 part (w/w).

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

Ph. Eur. 6.2 (Oxprenolol Hydrochloride). A white or almost white, crystalline powder. Very soluble in water; freely soluble in alcohol. A 10% solution in water has a pH of 4.5 to 6.0. Protect from light.

USP 31 (Oxprenolol Hydrochloride). A white crystalline powder. Freely soluble in water, in alcohol, and in chloroform; sparingly soluble in acetone; practically insoluble in ether. A 10% solution in water has a pH of 4.0 to 6.0.

Adverse Effects, Treatment, and Precautions

As for Beta Blockers, p.1226.

Breast feeding. Oxprenolol is distributed into breast milk but the amount likely to be ingested by an infant is small (see under Pharmacokinetics, below). No adverse effects have been seen in breast-fed infants whose mothers were given oxprenolol and the American Academy of Pediatrics considers¹ that it is therefore usually compatible with breast feeding.

1. American Academy of Pediatrics. The transfer of drugs and other chemicals into human milk. *Pediatrics* 2001; **108**: 776–89. Correction. *ibid*: 1029. Also available at: <http://aappolicy.aappublications.org/cgi/content/full/pediatrics%3b108/3/776> (accessed 10/01/08)

Hypersensitivity. Oxprenolol-induced drug fever has been reported¹ in a patient and was confirmed by a challenge test.

1. Hasegawa K, *et al.* Drug fever due to oxprenolol. *BMJ* 1980; **281**: 27–8.

Overdosage. Rhabdomyolysis with myoglobinuria has been reported¹ as a complication of severe overdosage with oxprenolol.

1. Schofield PM, *et al.* Recovery after severe oxprenolol overdose complicated by rhabdomyolysis. *Hum Toxicol* 1985; **4**: 57–60.

Interactions

The interactions associated with beta blockers are discussed on p.1228.

Pharmacokinetics

Oxprenolol is well absorbed from the gastrointestinal tract, but is subject to first-pass metabolism resulting in

variable bioavailability (20 to 70%). Peak plasma concentrations occur about 1 or 2 hours after a dose. Oxprenolol is about 80% bound to plasma proteins. It crosses the placenta and is distributed into breast milk. It is moderately lipid-soluble and crosses the blood-brain barrier. Oxprenolol is metabolised in the liver and almost entirely excreted in the urine. An elimination half-life of 1 to 2 hours has been reported.

Pregnancy and breast feeding. The placental transfer of oxprenolol and its passage into breast milk was studied¹ in 32 pregnant women given a preparation containing oxprenolol and dihydralazine (*Trasipressol*). At delivery the mean maternal plasma concentration was 0.386 nanomoles/mL compared with 0.071 and 0.081 nanomoles/mL in plasma from the umbilical artery and vein respectively. Oxprenolol plasma concentrations in the newborn ranged from 0 to 0.186 nanomoles/mL during the first 24 hours of life. The concentrations of oxprenolol in breast milk 3 to 6 days after delivery ranged from 0 to 1.342 nanomoles/mL, and the milk to plasma concentration ratio was 0.45:1. Based on the highest milk concentration seen it was calculated that a breast-fed infant could receive, at a maximum, a daily dose at least 60 times less than an average adult daily dose (240 mg daily) for hypertension. In another study² in 12 women given oxprenolol, mean milk to plasma concentration ratios were 0.21:1 to 0.43:1, depending on dose.

1. Sioufi A, *et al.* Oxprenolol placental transfer, plasma concentrations in newborns and passage into breast milk. *Br J Clin Pharmacol* 1984; **18**: 453–6.

2. Fidler J, *et al.* Excretion of oxprenolol and timolol in breast milk. *Br J Obstet Gynaecol* 1983; **90**: 961–5.

Uses and Administration

Oxprenolol is a non-cardioselective beta blocker (p.1225). It is reported to possess intrinsic sympathomimetic and membrane-stabilising activity.

Oxprenolol is given orally as the hydrochloride in the management of hypertension (p.1171), angina pectoris (p.1157), and cardiac arrhythmias (p.1160). It is also used in anxiety disorders (p.952).

In **hypertension** oxprenolol hydrochloride is given in a usual dose of 80 to 160 mg daily in two or three divided doses. The dose may be increased at weekly or fortnightly intervals until a satisfactory response is achieved. The usual maximum dose is 320 mg daily although up to 480 mg daily has been given.

The usual dose for **angina pectoris** is 80 to 160 mg daily in two or three divided doses with a usual maximum of 320 mg daily.

For **cardiac arrhythmias** a dose of 40 mg daily to not more than 240 mg daily in two or three divided doses may be used.

To relieve **anxiety** in stressful situations oxprenolol hydrochloride is given in usual doses of 40 to 80 mg daily, either as a single dose or in two divided doses.

Modified-release preparations allowing once daily dosing are also available.

Preparations

BP 2008: Oxprenolol Tablets;

USP 31: Oxprenolol Hydrochloride Extended-release Tablets; Oxprenolol Hydrochloride Tablets.

Proprietary Preparations (details are given in Part 3)

Austral.: Corbeton; **Austria:** Trasicor; **Canad.:** Slow-Trasicor†; Trasicor; **Denm.:** Trasicor†; **Fr.:** Trasicor; **Ger.:** Trasicor; **Gr.:** Trasicor; **Hung.:** Trasicor†; **Neth.:** Trasicor; **NZ:** Captol†; Slow-Trasicor†; **Spain:** Trasicor; **Switz.:** Slow-Trasicor; Trasicor; **Turk.:** Trasicor; **UK:** Slow-Trasicor; Trasicor.

Multi-ingredient: **Austria:** Trasitensin; Trepress; **Fr.:** Trasitensin; **Ger.:** Impresso†; Trasitensin†; Trepress; **Gr.:** Trasitensin; **Ital.:** Trasitensin; **Spain:** Trasitensin; **Switz.:** Slow-Trasitensin; **UK:** Trasidrex.

Oxyfedrine Hydrochloride (BANM, rINNM)

D-563; Hidrocloruro de oxifedrina; Oxifedrini Chloridum; Oxyfedrine, Chlorhydrate d'; Oxifedrini Hydrochloridum. L-3-(β-Hydroxy-α-methylphenethylamino)-3'-methoxypropiofenone hydrochloride.

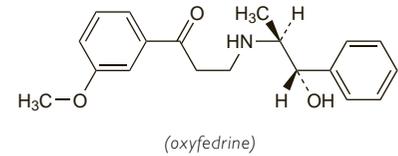
Оксифедрина Гидрохлорид

C₁₉H₂₃NO₃·HCl = 349.9.

CAS — 15687-41-9 (oxyfedrine); 16777-42-7 (oxyfedrine hydrochloride).

ATC — C01DX03.

ATC Vet — QC01DX03.



(oxyfedrine)

Profile

Oxyfedrine hydrochloride has vasodilator properties and has been used in angina pectoris, and myocardial infarction. It is metabolised to phenylpropanolamine (p.1569).

Preparations

Proprietary Preparations (details are given in Part 3)

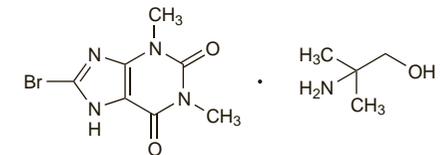
Austria: Ildamen; **Cz.:** Myofedrin†; **Ger.:** Ildamen†; Myofedrin†; **India:** Ildamen; **Philipp.:** Ildamen; **Port.:** Ildamen.

Pamabrom (USAN) ⊗

Pamabromo. 2-Amino-2-methylpropan-1-ol 8-bromotheophyllinate.

C₄H₁₁NO₇·C₇H₇BrN₄O₂ = 348.2.

CAS — 606-04-2.



Pharmacopoeias. In *US.*

Profile

Pamabrom is a weak diuretic that has been used, with analgesics and antihistamines, for symptomatic relief of the premenstrual syndrome.

Preparations

Proprietary Preparations (details are given in Part 3)

USA: Maximum Strength Aqua-Ban.

Multi-ingredient: **Arg.:** Everfem; **Canad.:** Extra Strength Multi-Symptom PMS Relief†; Midol PMS Extra Strength; Painaid PMF; Pamprin; Relievol PMS; Trendar PMS†; Tylenol Menstrual; **Chile:** Kitadol Periodo Menstrual; Minfacien; Preudal; Tapsin Periodo Menstrual; **Malaysia:** Panadol Menstrual; **Mex.:** Femsedin Kutz; **Singapore:** Panadol Menstrual; **USA:** Fem-1†; Lurline PMS; Midol Pre-Menstrual Syndrome; Midol Teen Formula; Painaid PMF Premenstrual Formula; Pamprin; Premsyn PMS; Womens Tylenol Multi-Symptom Menstrual Relief.

Pamiteplase (rINM)

Pamiteplasa; Pamiteplase; Pamiteplasum; YM-866. 275-L-Glutamic acid-(1-91)-(174-527)-plasminogen activator (human tissue-type protein moiety).

Памитеплаза

CAS — 151912-42-4.

Profile

Pamiteplase is a thrombolytic related to alteplase (p.1207) used in acute myocardial infarction. It has been investigated in ischaemic stroke.

Preparations

Proprietary Preparations (details are given in Part 3)

Jpn.: Solinase†.

Pantethine

Pantetina. (R)-NN'-[Dithiobis(ethylamine)carbonyl(ethylene)]-bis(2,4-dihydroxy-3,3-dimethylbutylamide).

Пантетин

C₂₂H₄₂N₄O₈S₂ = 554.7.

CAS — 16816-67-4.

ATC — A11HA32.

ATC Vet — QA11HA32.



Pharmacopoeias. In *Jpn.*

Profile

Pantethine, a derivative of pantothenic acid (p.1959), is a component of coenzyme A. It is used as a lipid regulating drug in the