absorption is a problem, in disaccharide intolerance (without isomaltose intolerance), and in acute and chronic hepatic and renal diseases where protein, mineral, and fluid restriction are often necessary.

Maltodextrin is also employed as a pharmaceutical excipient.

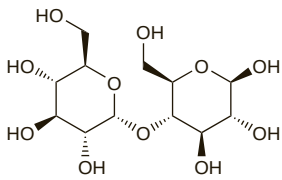
Preparations

Proprietary Preparations (details are given in Part 3)
Arg.: Carbohidrato 100; MC Modulo Calorico; ***Austral.:*** Maxijul; ***Braz.:*** Nidex; Oligossac†; ***Canad.:*** Moducal†; ***Chile:*** Modulo Calorico; ***Cz.:*** Fantomalt†; ***Fin.:*** Fantomalt; ***Hong Kong:*** Fiber Basics; ***Ital.:*** Energen; Fantomalt; Maltovis; Nidex; ***NZ:*** Moducal; ***Port.:*** Fantomalt†; Moducal†; ***USA:*** Moducal; ***Venez.:*** Fantomalt.

Multi-ingredient: ***Chile:*** Nutrasweet†; ***Fr.:*** Gumilk; ***Indon.:*** Fantomalt; ***Ital.:*** Giflorex; ***Pol.:*** Fantomalt; ***Venez.:*** Glutapak; Glutapak-R; Hermesetas Gold; Modulo Calorico; Multidex.

Maltose

D-maltose; Maltobiose; Maltosa. 4-*O*-α-D-Glucopyranosyl-β-D-glucopyranose.
$C_{12}H_{22}O_{11}$ = 342.3.
CAS — 69-79-4 (anhydrous maltose); 6363-53-7 (maltose monohydrate).



(anhydrous maltose)

Pharmacopoeias. *Jpn* includes the monohydrate. *USNF* permits the anhydrous and monohydrate forms.
USNF 26 (Maltose). It contains one molecule of water of hydration or is anhydrous. A white, odourless, crystalline powder that has a sweet taste. Freely soluble in water; very soluble in dehydrated alcohol; practically insoluble in ether; slightly soluble in methyl alcohol. pH of a 10% solution in water is between 3.7 and 4.7 (anhydrous form) and between 4.0 and 5.5 (monohydrate form).

Profile

Maltose, a disaccharide composed of two glucose molecules, is less sweet than sucrose. It is obtained from starch by hydrolysis with amylase. Maltose is often present with other sugars in mixtures used as carbohydrate sources. It is also used as a pharmaceutical excipient.

Adverse effects. Hyponatraemia developed after intravenous infusion of normal immunoglobulin in 10% maltose in a patient with acute renal failure after liver transplantation.[1] The effect, which recurred on each of four successive infusions, resembled that of hyperglycaemia and was thought to be due to accumulation of maltose and other osmotically active metabolites in the extracellular fluid.

1. Palevsky PM, *et al.* Maltose-induced hyponatremia. *Ann Intern Med* 1993; **118:** 526–8.

Precautions. Preparations that contain, or are metabolised to, maltose may interfere with the results from glucose tests (p.2314). Overestimation of glucose results may mask hypoglycaemia, resulting in the inappropriate use of insulin.[1,2] The problem may also occur with icodextrin, which produces maltose as a metabolite (see Dialysis, p.1937).

1. Medicines and Healthcare products Regulatory Agency. Medical device alert: ref MDA/2007/058 issued 19 July 2007. Available at: http://www.mhra.gov.uk/PrintPreview/PublicationSP/CON2031807 (accessed 01/07/08)
2. FDA. Important safety information on interference with blood glucose measurement following use of parenteral maltose/parenteral galactose/oral xylose-containing products (issued November 2005). Available at: http://www.fda.gov/cber/safety/maltose110405.htm (accessed 01/07/08)

Preparations

USNF 26: Liquid Glucose.

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

Multi-ingredient: ***Fr.:*** Picot†.

Manganese

Mangan; Manganèse; Manganeso; Manganum.
Mn = 54.938045.
CAS — 7439-96-5.

Manganese Chloride

Manganeso, cloruro de.
$MnCl_2.4H_2O$ = 197.9.
CAS — 7773-01-5 (anhydrous manganese chloride); 13446-34-9 (manganese chloride tetrahydrate).

Pharmacopoeias. In *US.*
USP 31 (Manganese Chloride). Large, irregular, pink, odourless, translucent crystals. Soluble in water and in alcohol; insoluble in ether. Store in airtight containers. pH of a 5% solution in water is between 3.5 and 6.0.

Manganese Gluconate

Manganèse, gluconate de; Manganeso, gluconato de; Mangani gluconas. Bis(D-gluconato-O^1,O^2) manganese; Manganese D-gluconate.
$C_{12}H_{22}MnO_{14}$ = 445.2.

Pharmacopoeias. In *Eur.* (see p.vii), which allows either anhydrous or hydrated forms, and in *US*, which allows either anhydrous or the dihydrate.
Ph. Eur. 6.2 (Manganese Gluconate). A white or pale pink, slightly hygroscopic, crystalline powder. Soluble in water; practically insoluble in anhydrous ethanol; insoluble in dichloromethane. Store in non-metallic, airtight containers.
USP 31 (Manganese Gluconate).

Manganese Sulfate

Mangaanisulfaattimonohydraatti; Manganèse (sulfate de) monohydraté; Manganese Sulphate; Manganeso, sulfato de; Mangani Sulfas; Mangani sulfas monohydricum; Mangán(II)-szulfát-monohidrát; Mangano sulfatas; Mangansulfatmonohydrat; Manganu siarczan; Síran manganatý. Manganese (II) sulphate monohydrate.
$MnSO_4.H_2O$ = 169.0.
CAS — 7785-87-7 (anhydrous manganese sulfate); 10034-96-5 (manganese sulfate monohydrate); 10101-68-5 (manganese sulfate tetrahydrate).

Pharmacopoeias. In *Eur.* (see p.vii) and *US. Br.* and *Fr.* also include the tetrahydrate.
BP 2008 (Manganese Sulphate). The tetrahydrate occurs as pale pink, odourless or almost odourless, crystals or crystalline powder. Freely soluble in water; practically insoluble in alcohol.
Ph. Eur. 6.2 (Manganese Sulphate Monohydrate). It occurs as a pale pink, slightly hygroscopic, crystalline powder. Freely soluble in water; practically insoluble in alcohol.
USP 31 (Manganese Sulfate). The monohydrate occurs as pale red, slightly efflorescent crystals, or as a purple, odourless powder. Soluble in water; insoluble in alcohol. Store in airtight containers at a temperature of 25°, excursions permitted between 15° and 30°.

Adverse Effects and Precautions

Acute poisoning due to ingestion of manganese or manganese salts is rare. The main symptoms of chronic poisoning, either from injection or usually inhalation of manganese dust or fumes in air, include extrapyramidal effects which may be followed by progressive deterioration in the CNS. Parenteral manganese should be used cautiously in patients with reduced biliary excretion, especially in cholestatic liver disease. When the duration of total parenteral nutrition is likely to exceed 1 month, serum-manganese concentration and liver function should be checked before starting treatment and regularly during treatment; additives containing manganese should be stopped if serum-manganese concentrations are raised or cholestasis develops.

Accumulation. There are reports of cholestatic liver disease, and possibly changes in the basal ganglia, associated with hypermanganesaemia in children given long-term parenteral nutrition;[1,2] manganese accumulation may be secondary to impaired biliary excretion.[3] Manganese supplementation in such patients requires re-appraisal and whole blood manganese concentrations should be monitored regularly. A low-dose regimen of not more than 1 microgram/kg (0.018 micromoles/kg) daily has been suggested,[2,3] a dose that was also recommended by the American Society for Parenteral and Enteral Nutrition.[4] Hypermanganesaemia and basal ganglia manganese deposition resolved over time in 2 children when the manganese dose in their parenteral nutrition was reduced.[5] Manganese accumulation in the basal ganglia has been seen in patients with liver cirrhosis,[6,7] and may be associated with parkinsonism[7,8] (for reference to the use of aminosalicylic acid in the treatment of manganese-induced parkinsonism, see p.202). Concern has been expressed[9] at the high levels of manganese contained in infant formulas.

1. Reynolds AP, *et al.* Manganese in long term paediatric parenteral nutrition. *Arch Dis Child* 1994; **71:** 527–8.
2. Fell JME, *et al.* Manganese toxicity in children receiving long-term parenteral nutrition. *Lancet* 1996; **347:** 1218–21.
3. Beath SV, *et al.* Manganese toxicity and parenteral nutrition. *Lancet* 1996; **347:** 1773–4. Correction. *ibid.* **348:** 416.
4. Mirtallo J, *et al.* American Society for Parenteral and Enteral Nutrition. Safe practices for parenteral nutrition. *J Parenter Enteral Nutr* 2004; **28:** S39–S70.
5. Kafritsa Y, *et al.* Long term outcome of brain manganese deposition in patients on home parenteral nutrition. *Arch Dis Child* 1998; **79:** 263–5.
6. Krieger D, *et al.* Manganese and chronic hepatic encephalopathy. *Lancet* 1995; **346:** 270–4.
7. Burkhard PR, *et al.* Chronic parkinsonism associated with cirrhosis. *Arch Neurol* 2003; **60:** 521–8.
8. Zatta P, *et al.* The role of metals in neurodegenerative processes: aluminum, manganese, and zinc. *Brain Res Bull* 2003; **62:** 15–28.
9. Hozyasz KK, Ruszczynska A. High manganese levels in milk-based infant formulas. *Neurotoxicology* 2004; **25:** 733.

Pharmacokinetics

Absorption of manganese from the gastrointestinal tract is variable, ranging from 3 to 50%. There is some evidence that the amount absorbed decreases as intake increases, suggesting a homoeostatic response. In the circulation, manganese is bound to transmanganin, a beta-1-globulin. Manganese is stored in the brain, kidneys, pancreas, and liver. It is excreted in bile, and undergoes enterohepatic circulation.

Uses and Administration

Manganese is an essential trace element and small amounts of a salt such as the chloride or sulfate are sometimes added to solutions for total parenteral nutrition. Suggested doses are 275 micrograms (5 micromoles) elemental manganese daily for adults and children over 40 kg, and 1 microgram/kg (0.0182 micromol/kg) daily for infants and children to a maximum of 15 micrograms (see also Accumulation, above).

Manganese compounds or salts that have been used in therapeutics in addition to those mentioned above include manganese amino acid chelate, manganese dioxide, manganese gluconate, and manganese hydrogen citrate.

Human requirements. In the UK neither a reference nutrient intake (RNI) nor an estimated average requirement (EAR) (see p.1925) has been set for manganese although a safe intake for adults was believed to lie above 1.4 mg (26 micromoles) daily.[1] Similarly, in the USA a recommended dietary allowance has not been published, although an adequate intake has been estimated to be 2.3 mg daily for men and 1.8 mg daily for women.[2] A tolerable upper intake level of 11 mg has also been set.[2] WHO has not proposed a safe range of mean population intakes for manganese since neither intakes resulting in deficiency nor threshold toxicity levels have been established.[3] Diets high in unrefined cereals, nuts, leafy vegetables, and tea will be high in manganese.

1. DoH. Dietary reference values for food energy and nutrients for the United Kingdom: report of the panel on dietary reference values of the committee on medical aspects of food policy. *Report on health and social subjects 41.* London: HMSO, 1991.
2. Standing Committee on the Scientific Evaluation of Dietary Reference Intakes of the Food and Nutrition Board. *Dietary Reference Intakes for vitamin A, vitamin K, arsenic, boron, chromium, copper, iodine, iron, manganese, molybdenum, nickel, silicon, vanadium, and zinc*. Washington DC: National Academy Press, 2001. Also available at: http://www.nap.edu/openbook.php?isbn=0309072794 (accessed 21/07/08)
3. WHO. Manganese. In: *Trace elements in human nutrition and health*. Geneva: WHO, 1996; 163–7.

Preparations

BPC 1973: Compound Ferrous Sulphate Tablets;
USP 31: Manganese Chloride for Oral Solution; Manganese Chloride Injection; Manganese Sulfate Injection.

Proprietary Preparations (details are given in Part 3)
Fr.: Mangaplexe†; ***Mex.:*** MN-Fusin†.

Multi-ingredient: ***Austral.:*** Bio Magnesium; Bioglan Joint Mobility; ***Braz.:*** Eviprostat†; Xantina B12†; Xantinon B12; ***Fr.:*** Cicaplast; Oligoderm; Oligorhine Manganese; ***Ger.:*** Algosteril Trionic†; ***Indon.:*** Eviprostat; Fitbon; Fitbon Plus; ***Irl.:*** Ferrotab†; ***Ital.:*** Sterimar Mn; ***Mex.:*** Actiman; ***Philipp.:*** Ruflex; ***Rus.:*** Tot'Hema (Тотема); ***S.Afr.:*** Ferrous Sulphate Compound; ***Singapore:*** Arthro-Flex; Eviprostat.

Medium-chain Triglycerides

Keskipitkäketjuiset tyydyttyneet triglyseridit; Triacylglyceroly střední nasycené; Triglicéridai, vidutinės grandinės; Trigliceridek, közepes szénláncú zsírsavaké; Triglicéridos de cadena media; Triglycerida saturata media; Triglycerider, medellångkedjiga; Triglycérides à chaîne moyenne.

Pharmacopoeias. In *Eur.* (see p.vii). Also in *USNF.*
Ph. Eur. 6.2 (Triglycerides, Medium-chain). They are obtained from the oil extracted from the hard, dried fraction of the endosperm of *Cocos nucifera* or from the dried endosperm of *Elaeis guineensis*. They consist of a mixture of triglycerides of saturated fatty acids, mainly of octanoic acid and of capric acid ($C_{10}H_{20}O_2$ = 172.3). They contain not less than 95% of saturated fatty acids with 8 and 10 carbon atoms. A colourless or slightly yellowish, oily liquid. Practically insoluble in water; miscible with alcohol, with dichloromethane, with petroleum spirit, and with fatty oils. Store in well-filled containers. Protect from light.
USNF 26 (Medium-Chain Triglycerides). They are obtained from the oil extracted from the hard, dried fraction of the endosperm of *Cocos nucifera* or from the dried endosperm of *Elaeis guineensis*. They consist of a mixture of triglycerides of saturated fatty acids, mainly of octanoic acid and of capric acid ($C_{10}H_{20}O_2$ = 172.3). They contain not less than 95% of saturated fatty acids with 8 and 10 carbon atoms. A colourless or slightly yellowish, oily liquid. Practically insoluble in water; miscible with alcohol, with dichloromethane, with petroleum spirit, and with fatty oils. Store in airtight containers at a temperature not exceeding 25°. Protect from light.

Profile

Medium-chain triglycerides are used for enteral and parenteral nutrition (p.1923) in conditions associated with malabsorption of fat, such as cystic fibrosis, enteritis, and steatorrhoea, and after intestinal resection. Medium-chain triglycerides are more readily hydrolysed than long-chain triglycerides and are not dependent

upon biliary or pancreatic secretions for absorption from the gastrointestinal tract. They provide 35 kJ (8.3 kcal) per g. They do not provide essential fatty acids.

Medium-chain triglycerides have also been used as bases for pharmaceutical preparations.

Preparations

Proprietary Preparations (details are given in Part 3)

Arg.: Teceeme; ***Austral.:*** Liquigen; MCT Oil; ***Canad.:*** MCT Oil†; ***Fin.:*** Liquigen; MCT Olja; ***Fr.:*** Liquigen; ***Gr.:*** MCT Oil; ***Hung.:*** Structolipid; ***Israel:*** MCT; ***Ital.:*** MCT; Mytic 810; ***Malaysia:*** MCT Oil†; ***NZ:*** Liquigen; MCT Oil; ***Port.:*** MCT Oil; ***Singapore:*** MCT†; ***UK:*** Alembicol D; MCT Oil; ***USA:*** MCT.

Multi-ingredient: ***Arg.:*** Lipofundin MCT/LCT-E; Lipofundin MCT/LCT†; ***Austral.:*** Caprilon; MCT Duocal; ***Austria:*** Lipofundin mit MCT; SMOFlipid; Structolipid; ***Belg.:*** Medialipide†; ***Chile:*** Lipofundin MCT/LCT; Lipovenos MCT/LCT; ***Cz.:*** Lipofundin MCT/LCT; Lipoplus; Nutriflex Lipid; SMOFlipid; Structolipid; ***Denm.:*** SMOFlipid; Structolipid; ***Fin.:*** Lipoplus; Nutriflex Lipid; Structolipid; Vasolipid; ***Fr.:*** Liprocil; Medialipide; Structolipide; ***Ger.:*** Gleitgelen; Lipofundin MCT; Lipovenos MCT; Nutriflex Lipid; SMOFlipid; Visine Trockene Augen; ***Gr.:*** Lipofundin MCT/LCT; SMOFlipid; Structolipid; ***Hong Kong:*** Lipofundin MCT/LCT; Nutriflex Lipid; ***Hung.:*** Lipofundin MCT; Lipovenos PLR†; SMOFlipid; ***Indon.:*** Lipofundin MCT/LCT; ***Irl.:*** Caprilon; Liquigen; MCT Duocal†; ***Israel:*** Lipofundin MCT/LCT; ***Ital.:*** Caprilon; Lipofundin MCT; Nutriperi Lipid; Nutriplus Lipid; Nutrispecial Lipid; Structolipid; ***Mex.:*** Lipofundin MCT/LCT; Lipovenoes MCT†; ***Neth.:*** Lipofundin MCT/LCT; Lipoplus; Nutriflex Lipid; SMOFlipid; Structolipid; ***Norw.:*** Nutriflex Lipid; SMOFlipid; Structolipid; Vasolipid; ***NZ:*** Structolipid; ***Pol.:*** Lipofundin MCT/LCT; SMOFlipid; ***Port.:*** Lipofundina MCT/LCT; Lipoplus; Nutribraun; Structolipid; ***S.Afr.:*** Lipofundin MCT/LCT; ***Singapore:*** Lipofundin MCT/LCT†; ***Spain:*** Lipofundina MCT/LCT; Nutriflex Lipid; Structolipid; ***Swed.:*** Lipoplus; Nutriflex Lipid; SMOFlipid; Structolipid; Vasolipid; ***Switz.:*** Lipofundin MCT/LCT; Nutriflex Lipid; Structolipid; ***Thai.:*** Lipofundin MCT/LCT; Structolipid; ***Turk.:*** Lipofundin MCT/LCT; ***UK:*** Caprilon; Imuderm; Lipidem; Lipofundin MCT/LCT; Liquigen; MCT Duocal; SMOFlipid; Structolipid; ***Venez.:*** Lipofundin MCT/LCT; Propol†.

Molybdenum

Molibdeno; Molybdän; Molybdène.

Mo = 95.96.

Ammonium Molybdate

Amonowy molibdenian; Molibdato de amonio. Hexaammonium molybdate tetrahydrate.

$(NH_4)_6Mo_7O_{24},4H_2O$ = 1236.0.

CAS — 12054-85-2.

Pharmacopoeias. In *US.*

USP 31 (Ammonium Molybdate). Colourless or slightly greenish or yellowish crystals. Soluble in water; practically insoluble in alcohol. Store in airtight containers.

Sodium Molybdate

Molibdato de sodio; Molybdenan sodný dihydrát; Natrii molybdas dihydricus; Natrio molibdatas dihidratas; Nátrium-molibdenát-dihidrát; Natriummolybdaattidihydraatti; Natriummolybdatdihydrat; Sodium (molybdate de) dihydraté; Sodu molibdenian.

$Na_2MoO_4,2H_2O$ = 242.0.

Pharmacopoeias. In *Eur.* (see p.vii). *Ger.* also includes a monograph for the anhydrous substance.

Ph. Eur. 6.2 (Sodium Molybdate Dihydrate). A white or almost white powder or colourless crystals. Freely soluble in water.

Adverse Effects

Very high intakes of molybdenum, and associated increases in xanthine oxidase activity, may result in hyperuricaemia, and possibly gout. Molybdenum intoxication may impair the utilisation of copper.

Uses and Administration

Molybdenum is an essential trace element and small amounts, in the form of ammonium molybdate or sodium molybdate, are sometimes added to solutions for total parenteral nutrition. A suggested dose is about 20 to 120 micrograms (0.2 to 1.2 micromoles) elemental molybdenum daily.

Ammonium molybdate is used in veterinary medicine to treat copper poisoning in sheep.

Human requirements. In the UK neither a reference nutrient intake (RNI) nor an estimated average requirement (EAR) (see p.1925) has been set for molybdenum although a safe intake was believed to be between 50 and 400 micrograms (0.5 and 4 micromoles) daily for adults.[1] In the USA, the recommended dietary allowance is 45 micrograms daily for adults.[2] The tolerable upper intake level is 2 mg daily.[2] WHO make the suggestion that the adult basal requirement for molybdenum could be about 25 micrograms daily,[3] corresponding to approximately 400 nanograms/kg.

Foods contributing to dietary molybdenum include milk, beans, breads, and cereals; however, extreme regional variations occur in molybdenum contents of food crops due to soil differences.

1. DoH. Dietary reference values for food energy and nutrients for the United Kingdom: report of the panel on dietary reference values of the committee on medical aspects of food policy. *Report on health and social subjects 41.* London: HMSO, 1991.
2. Standing Committee on the Scientific Evaluation of Dietary Reference Intakes of the Food and Nutrition Board. *Dietary Reference Intakes for vitamin A, vitamin K, arsenic, boron, chromium, copper, iodine, iron, manganese, molybdenum, nickel, silicon, vanadium, and zinc.* Washington DC: National Academy Press, 2001. Also available at: http://www.nap.edu/openbook.php?isbn=0309072794 (accessed 21/07/08)
3. WHO. Molybdenum. In: *Trace elements in human nutrition and health.* Geneva: WHO, 1996; 144–54.

Preparations

USP 31: Ammonium Molybdate Injection.

Proprietary Preparations (details are given in Part 3)

Fr.: Molybdene Injectable; ***USA:*** Molypen.

Neohesperidin Dihydrochalcone

E959; Neohesperidiinidihydrokalkoni; Neohesperidin DC; Neohesperidin-dihidrochalkonas; Neohesperidin-dihydrochalconum; Neohesperidin-dihydrochalkon; Neohesperidindivätekalkon; Neoheszperidin-dihidro-kalkon; NHDC. 3,5-Dihydroxy-4-[3-(3-hydroxy-4-methoxyphenyl)propionyl]phenyl 2-*O*-(6-deoxy-α-L-mannopyranosyl)-β-D-glucopyranoside.

$C_{28}H_{36}O_{15}$ = 612.6.

CAS — 13241-33-3 (neohesperidin); 20702-77-6 (neohesperidin dihydrochalcone); 18916-17-1 (naringin dihydrochalcone); 65520-51-6 (neoeriocitrin dihydrochalcone).

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

Ph. Eur. 6.2 (Neohesperidin-dihydrochalcone). A white or yellowish-white powder. Practically insoluble in water and in dichloromethane; freely soluble in dimethyl sulfoxide; soluble in methyl alcohol. Protect from light.

Profile

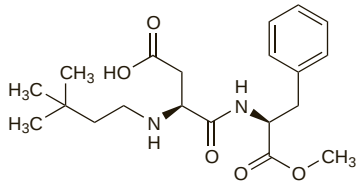
Neohesperidin dihydrochalcone is an intense sweetener derived from naringin, a flavonoid present in citrus peel. It is about 1000 to 1500 times as sweet as sucrose and is used in foods, beverages, and pharmaceuticals. It has a synergistic sweetening effect when used with other sweeteners.

Neotame

Neotamo. *N*-[*N*-(3,3-Dimethylbutyl)-L-α-aspartyl]-L-phenylalanine 1-methyl ester.

$C_{20}H_{30}N_2O_5$ = 378.5.

CAS — 165450-17-9.



Pharmacopoeias. In *USNF.*

USNF 26 (Neotame). Store in a dry place at a temperature not exceeding 40°.

Profile

Neotame is an intense sweetener used in foods and beverages. It has between 7000 and 13 000 times the sweetening power of sucrose and is stable to heat.

◊ References.

1. Anonymous. Neotame—a new artificial sweetener. *Med Lett Drugs Ther* 2002; **44:** 73–4.

Nicotinamide Ascorbate *(rINNM)*

Ascorbato de nicotinamida; Niacinamide Ascorbate; Nicoscorbine; Nicotinamide, Ascorbate de; Nicotinamidi Ascorbas.

Никотинамида Аскорбат

$C_{12}H_{14}N_2O_7$ = 298.2.

CAS — 1987-71-9.

Profile

Nicotinamide ascorbate is a complex of nicotinamide (p.1957) with ascorbic acid (p.1983) that is used in multivitamin preparations. It has also been given with betaine glucuronate and dilolamine glucuronate for liver disorders.

Preparations

Proprietary Preparations (details are given in Part 3)

Multi-ingredient: ***Hong Kong:*** Jetepar; ***Ital.:*** Ietepar†; ***Malaysia:*** Jetepar; ***Philipp.:*** Jetepar; ***Singapore:*** Jetepar.

Nicotinic Acid *(rINN)*

375; Acide nicotinique; Ácido nicotínico; Acidum nicotinicum; Kwas nikotynowy; Kyselina nikotinová; Niacin; Nikotiinihappo; Nikotinik Asit; Nikotino rūgštis; Nikotinsäure; Nikotinsav; Nikotinsyra. Pyridine-3-carboxylic acid.

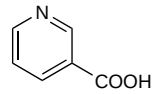
Никотиновая Кислота

$C_6H_5NO_2$ = 123.1.

CAS — 59-67-6.

ATC — C04AC01; C10AD02.

ATC Vet — QC04AC01; QC10AD02.



NOTE. Some published sources use the term niacin as a generic term to include both nicotinic acid and nicotinamide.

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

Ph. Eur. 6.2 (Nicotinic Acid). A white or almost white, crystalline powder. Sparingly soluble in water; soluble in boiling water and in boiling alcohol. It dissolves in dilute solutions of alkali hydroxides and carbonates. Protect from light.

USP 31 (Niacin). White crystals or crystalline powder, odourless or has a slight odour. Soluble 1 in 60 of water; freely soluble in boiling water, in boiling alcohol, and in solutions of alkali hydroxides and carbonates; practically insoluble in ether.

Nicotinamide *(rINN)*

Niacinamide; Nicotinamida; Nicotinamidum; Nicotinic Acid Amide; Nicotylamide; Nikotiiniamidi; Nikotinamid; Nikotinamidas; Nikotynamid; Vitamin B_3; Vitamin PP. Pyridine-3-carboxamide.

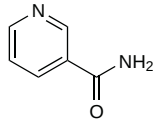
Никотинамид

$C_6H_6N_2O$ = 122.1.

CAS — 98-92-0.

ATC — A11HA01.

ATC Vet — QA11HA01.



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

Ph. Eur. 6.2 (Nicotinamide). A white or almost white, crystalline powder or colourless crystals. Freely soluble in water and in dehydrated alcohol. A 5% solution in water has a pH of 6.0 to 7.5.

USP 31 (Niacinamide). A white crystalline powder, odourless or practically so. Soluble 1 in 1.5 of water, 1 in 10 of boiling water, and 1 in 5.5 of alcohol; soluble in glycerol. Its solutions are neutral to litmus. Store in airtight containers.

Adverse Effects and Treatment

Nicotinic acid has a vasodilator action and when given by mouth or by injection in therapeutic doses it may cause flushing, a sensation of heat, faintness, and a pounding in the head. Flushing may be accompanied by dizziness, tachycardia, palpitations, dyspnoea, sweating, chills, or oedema. These symptoms are transient and various strategies have been proposed to reduce them (see Incidence of Adverse Effects, below). Nicotinamide does not have a vasodilator action.

Other adverse effects that have been reported, especially after high doses of nicotinic acid, include dryness of the skin, pruritus, hyperpigmentation, cramps, diarrhoea, nausea and vomiting, anorexia, activation of peptic ulcer, amblyopia, jaundice and impairment of liver function, decrease in glucose tolerance, hyperglycaemia, and hyperuricaemia. Most of these effects subside on withdrawal of the drug. Hypophosphataemia, a reduction in platelet counts, and prolongation of prothrombin time have also been reported. Insomnia, myalgia, hypotension, and rhinitis may occur rarely.