Ferrum Hausmann; Unifer†; ***Malaysia:*** Venofer; ***Mex.:*** Venoferrum; ***Neth.:*** Venofer; ***Norw.:*** Venofer; ***NZ:*** Venofer; ***Port.:*** Venofer; ***S.Afr.:*** Venofer; ***Singapore:*** Venofer; ***Spain:*** Feriv; Venofer; ***Swed.:*** Venofer; ***Switz.:*** Venofer; ***Thai.:*** Venofer; ***Turk.:*** Venofer; ***UK:*** Venofer; ***USA:*** Venofer; ***Venez.:*** Venofer.

Multi-ingredient: ***Ger.:*** Hicoton†; Junisana†; Selectafer N†.

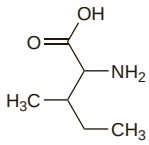
Isoleucine *(USAN, rINN)*

I; Ile; Isoleucin; Isoleucina; L-Isoleucine; Isoleucinum; Isoleusiini; Izoleucin; Izoleucinas. L-2-Amino-3-methylvaleric acid.

Изолейцин

$C_6H_{13}NO_2$ = 131.2.

CAS — 73-32-5.



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

Ph. Eur. 6.2 (Isoleucine). A white or almost white, crystalline powder or flakes. Sparingly soluble in water; slightly soluble in alcohol. It dissolves in dilute mineral acids and in dilute solutions of alkali hydroxides. Protect from light.

USP 31 (Isoleucine). White, practically odourless crystals. Soluble in water; slightly soluble in hot alcohol; insoluble in ether. pH of a 1% solution in water is between 5.5 and 7.0.

Profile

Isoleucine is a branched-chain aliphatic amino acid that is an essential constituent of the diet. It is used as a dietary supplement. It is also an ingredient of several preparations that have been promoted for disorders of the liver.

Preparations

Proprietary Preparations (details are given in Part 3)

Multi-ingredient: ***Ger.:*** Bramin-hepa†; Falkamin; ***Ital.:*** Falkamin†; Isobranch; Isoram.

Isomalt *(BAN)*

Bay-i-3930; E953; Isomalta; Isomalti; Isomaltitol; Isomaltum; Izomalt; Izomaltas; Palatinit.

CAS — 64519-82-0.

Pharmacopoeias. In *Eur.* (see p.vii). Also in *USNF*.

Ph. Eur. 6.2 (Isomalt). A mixture of 6-*O*-α-D-glucopyranosyl-D-glucitol ($C_{12}H_{24}O_{11}$ = 344.3) and 1-*O*-α-D-glucopyranosyl-D-mannitol dihydrate ($C_{12}H_{24}O_{11}$,$2H_2O$ = 380.3) and neither of the two components is less than 3%, calculated with reference to the anhydrous substance. A white or almost white powder or granules. Freely soluble in water; practically insoluble in dehydrated alcohol.

USNF 26 (Isomalt). 6-*O*-α-D-Glucopyranosyl-D-glucitol (1,6-GPS) and 1-*O*-α-D-glucopyranosyl-D-mannitol (1,1-GPM), and neither of the two components is less than 3.0% of the mixture, calculated on the anhydrous basis.

Profile

Isomalt is a sugar alcohol (polyol) used as a bulk sweetener in foods. The ingestion of large quantities may produce flatulence and have a laxative effect.

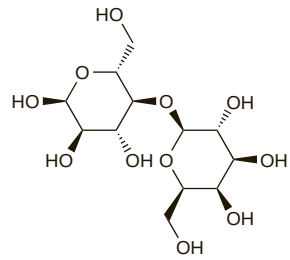
Metabolism. Isomalt is partly metabolised in the small intestine to glucose, mannitol, and sorbitol and the remaining isomalt is completely metabolised by the flora of the large intestine.[1] The Australian manufacturers have commented that the hydrolysis and absorption is minimal and does not significantly affect blood-sugar or insulin concentrations; they consider isomalt to be suitable for use by diabetic patients.[2]

1. FAO/WHO. Evaluation of certain food additives and contaminants: twenty-ninth report of the joint FAO/WHO expert committee on food additives. *WHO Tech Rep Ser 733* 1986.
2. Barnes JA. Martindale and isomalt. *Aust J Pharm* 1994; **75:** 183.

Lactose

Lactosa; Lactosum; Laktoosi; Laktos; Laktosa; Laktóz; Laktoza; Laktozé; Lattosio; Milk Sugar; Saccharum Lactis; Saccharum Lactis.

CAS — 63-42-3 (anhydrous lactose); 5989-81-1 (lactose monohydrate); 10039-26-6 (lactose monohydrate, cyclic); 64044-51-5 (lactose monohydrate, open form).



(anhydrous lactose)

Description. Lactose is a disaccharide obtained from the whey of milk. It may exist in a number of distinct forms depending upon the crystallisation and drying processes employed. The forms can vary in the contents of crystalline and amorphous lactose, the amounts of α-lactose (*O*-β-D-galactopyranosyl-(1→4)-α-D-glucopyranose) and β-lactose (*O*-β-D-galactopyranosyl-(1→4)-β-D-glucopyranose), and in their hydration states. The α-form of lactose exists in either the anhydrous ($C_{12}H_{22}O_{11}$ = 342.3) or monohydrate ($C_{12}H_{22}O_{11}$,H_2O = 360.3) state whereas the β-form exists only in the anhydrous state. Commercial lactose is mainly the α-monohydrate.

Pharmacopoeias. In *Chin.*, *Eur.* (see p.vii), *Int.*, *Jpn*, and *Viet.* Also in *USNF*. Some pharmacopoeias include separate monographs for anhydrous lactose and lactose monohydrate.

Ph. Eur. 6.2 (Lactose, Anhydrous). It is β-lactose or a mixture of α-lactose and β-lactose. A white or almost white, crystalline powder. Freely but slowly soluble in water; practically insoluble in alcohol.

Ph. Eur. 6.2 (Lactose Monohydrate; Lactose BP 2008). It is the monohydrate of α-lactose. It may be modified as to its physical characteristics and may contain varying proportions of amorphous lactose. A white or almost white, crystalline powder. Freely but slowly soluble in water; practically insoluble in alcohol. Store in airtight containers.

USNF 26 (Anhydrous Lactose). It is β-lactose or a mixture of α- and β-lactose. It is a white or almost white powder. Freely soluble in water; practically insoluble in alcohol. Store in airtight containers.

USNF 26 (Lactose Monohydrate). It is a natural disaccharide, obtained from milk, which consists of one glucose and one galactose moiety. It may be modified as to its physical characteristics, and may contain varying proportions of amorphous lactose. It is a white, free-flowing powder. Freely, but slowly soluble in water; practically insoluble in alcohol. Store in airtight containers.

Adverse Effects and Precautions

Lactose intolerance occurs due to a deficiency of the intestinal enzyme lactase. Ingestion of lactose by patients with lactase deficiency leads to a clinical syndrome of abdominal pain, diarrhoea, distension, and flatulence; symptoms may also occur in persons without such a deficiency who have ingested excessive amounts of lactose.

Lactose is contra-indicated in patients with galactosaemia, the glucose-galactose malabsorption syndrome, or lactase deficiency.

Lactose intolerance. Reviews of lactose intolerance.[1-3] The capacity of the infant intestine to produce lactase, the enzyme responsible for digesting lactose, is retained into adulthood only by a minority of the world's population, mostly in those of north European descent; in Africa and Asia more than 90% of the population are lactase deficient. Because of the ubiquity of lactose in the diet and the consequent frequency of abdominal symptoms, attempts have been made to treat lactose intolerance by dietary exclusion (which need not be complete since lactase deficiency is rarely absolute). An alternative is enzyme replacement therapy with β-galactosidase from micro-organisms (see Tilactase, p.2402), but the role of such therapy has yet to be fully determined. The findings of one study[4] suggested that, in adults with lactose intolerance, the use of lactose-digestive aids is unnecessary if lactose intake is limited to the equivalent of 240 mL of milk or less daily.

There has been concern that lactose might be contaminated with protein from milk, and it has been recommended that children with cow's milk allergy avoid lactose-containing foods. However, a small study[5] found that children allergic to cow's milk could still tolerate lactose.

For the use of soya in infants intolerant to cow's milk, see Food Intolerance, p.1967.

1. Anonymous. Lactose intolerance. *Lancet* 1991; **338:** 663–4.
2. Vesa TH, *et al.* Lactose intolerance. *J Am Coll Nutr* 2000; **19** (suppl): 165S–175S.
3. Heyman MB. Committee on Nutrition. Lactose intolerance in infants, children, and adolescents. *Pediatrics* 2006; **118:** 1279–86.
4. Suarez FL, *et al.* A comparison of symptoms after the consumption of milk or lactose-hydrolysed milk by people with self-reported severe lactose intolerance. *N Engl J Med* 1995; **333:** 1–4.
5. Fiocchi A, *et al.* Clinical tolerance to lactose in children with cows' milk allergy. *Pediatrics* 2003; **112:** 359–62.

Pharmacokinetics

Lactose is hydrolysed by lactase in the small intestine to glucose and galactose, which are then absorbed.

Uses and Administration

Lactose, the carbohydrate component of milk, is less sweet than sucrose.

Lactose is widely used as an excipient in pharmaceutical manufacturing. In the production of capsules or tablets it may be used as a diluent, bulking agent, or filler, and in powders as a bulking agent. Lactose is also used as a carrier for drugs in dry powder inhalers. Characteristics such as particle size or flow characteristics make different grades of lactose suitable for different applications.

Preparations

Proprietary Preparations (details are given in Part 3)

Multi-ingredient: ***Austria:*** Ichth-Oestren; ***Fr.:*** Tavag.

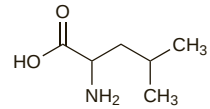
Leucine *(USAN, rINN)*

α-Aminoisocaproic Acid; L; Leu; Leucin; Leucina; Leucinas; L-Leucine; Leucinum; Leucyna; Leusiini. L-2-Amino-4-methylvaleric acid.

Лейцин

$C_6H_{13}NO_2$ = 131.2.

CAS — 61-90-5.



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

Ph. Eur. 6.2 (Leucine). A white or almost white, crystalline powder or shiny flakes. Sparingly soluble in water; practically insoluble in alcohol. It dissolves in dilute mineral acids and in dilute solutions of alkali hydroxides. Protect from light.

USP 31 (Leucine). White, practically odourless crystals. Sparingly soluble in water; insoluble in ether. pH of a 1% solution in water is between 5.5 and 7.0.

Profile

Leucine is a branched-chain aliphatic amino acid that is an essential constituent of the diet. It is used as a dietary supplement. It is also an ingredient of several preparations that have been promoted for disorders of the liver.

Preparations

Proprietary Preparations (details are given in Part 3)

Multi-ingredient: ***Fr.:*** Revitalose; ***Ger.:*** Bramin-hepa†; Falkamin; ***Ital.:*** Falkamin†; Isobranch; Isoram.

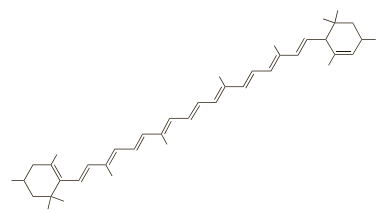
Lutein

E161(b); Xanthophyll. (3*R*,3′*R*,6′*R*)-β,ε-Carotene-3,3′-diol.

Лютеин

$C_{40}H_{56}O_2$ = 568.9.

CAS — 127-40-2.



Pharmacopoeias. In *US*.

US. also includes Lutein Preparation.

USP 31 (Lutein). A red crystalline powder. Soluble in dehydrated alcohol, in dichloromethane, and in ethyl acetate; partially soluble in hexane. Store at 8° to 15° in tightly-sealed, airtight containers. Protect from light and oxygen.

Profile
Lutein is a naturally occurring carotenoid that has been investigated for its supposed role in a number of conditions including age-related macular degeneration (p.785), cataracts, cardiovascular disease, and cancer.

Lutein is also used as a colouring agent.

◊ References.

1. Mares-Perlman JA, *et al.* The body of evidence to support a protective role for lutein and zeaxanthin in delaying chronic disease: overview. *J Nutr* 2002; **132** (suppl): 518S–524S.
2. Granado F, *et al.* Nutritional and clinical relevance of lutein in human health. *Br J Nutr* 2003; **90:** 487–502.
3. Mozaffarieh M, *et al.* The role of the carotenoids, lutein and zeaxanthin, in protecting against age-related macular degeneration: a review based on controversial evidence. *Nutr J* 2003; **2:** 20.
4. Trumbo PR, Ellwood KC. Lutein and zeaxanthin intakes and risk of age-related macular degeneration and cataracts: an evaluation using the Food and Drug Administration's evidence-based review system for health claims. *Am J Clin Nutr* 2006; **84:** 971–4.
5. Cho E, *et al.* Prospective study of lutein/zeaxanthin intake and risk of age-related macular degeneration. *Am J Clin Nutr* 2008; **87:** 1837–43.

Preparations
Proprietary Preparations (details are given in Part 3)
Fr.: Lutebiol.

Multi-ingredient: ***Indon.:*** Eyevit; Lutevision; Lutevision Extra; Lutevit; Matovit Fifty; Nuvision; Oculex; Optha-LL; Optimax; Reticopen; Retivit; Vita-Vision; ***Israel:*** Opti-safe; Opti-safe AREDS; ***Mex.:*** Snelvit; ***Philipp.:*** Nutrotal.

Lysine *(USAN, rINN)*
K; Lisina; Lys; L-Lysine; Lysinum. L-2,6-Diaminohexanoic acid.

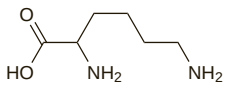
Лизин

$C_6H_{14}N_2O_2$ = 146.2.

CAS — 56-87-1.

ATC — B05XB03.

ATC Vet — QB05XB03.



Pharmacopoeias. In *Ger.* as the monohydrate.

Lysine Acetate *(rINNM)*
Acetato de lisina; Lizino acetatas; Lizyny octan; Lys Acetate; Lysiniasetaatti; Lysinacetat; Lysin-acetát; Lysine, acétate de; L-Lysine Monoacetate; Lysini acetas. L-2,6-Diaminohexanoic acid acetate.

Лизина Ацетат

$C_6H_{14}N_2O_2,C_2H_4O_2$ = 206.2.

CAS — 57282-49-2.

Pharmacopoeias. In *Chin.*, *Eur.* (see p.vii), and *US*.
Ph. Eur. 6.2 (Lysine Acetate). A white or almost white, crystalline powder or colourless crystals. It exhibits polymorphism. Freely soluble in water; very slightly soluble in alcohol. Protect from light.
USP 31 (Lysine Acetate). White, odourless crystals or crystalline powder. Freely soluble in water.

Lysine Hydrochloride *(USAN, rINNM)*
Hidrocloruro de lisina; Lizin-hidroklorid; Lizino hidrochloridas; Lys Hydrochloride; Lysiinihydrokloridi; Lysine, chlorhydrate de; L-Lysine Monohydrochloride; Lysin-hydrochlorid; Lysinhydroklorid; Lysini hydrochloridum. L-2,6-Diaminohexanoic acid hydrochloride.

Лизина Гидрохлорид

$C_6H_{14}N_2O_2$,HCl = 182.6.

CAS — 657-27-2.

Pharmacopoeias. In *Chin.*, *Eur.* (see p.vii), *Jpn*, and *US*.
Ph. Eur. 6.2 (Lysine Hydrochloride). A white or almost white, crystalline powder or colourless crystals. Freely soluble in water; slightly soluble in alcohol. Protect from light.
USP 31 (Lysine Hydrochloride). A white, odourless powder. Freely soluble in water.

Profile
Lysine is a basic amino acid that is an essential constituent of the diet. Lysine acetate and lysine hydrochloride are used as dietary supplements.

Lysinuric protein intolerance. For mention of the use of lysine to correct lysine deficiency in lysinuric protein intolerance, see Hyperammonaemia, under Citrulline, p.1935.

Preparations
USP 31: Lysine Hydrochloride Tablets.

Proprietary Preparations (details are given in Part 3)
Port.: Incremin†.

Multi-ingredient: ***Arg.:*** Latlas; ***Austral.:*** Cold Sore Relief†; Vitaline†; ***Fr.:*** Curasten; Revitalose; ***Hong Kong:*** Digezym; ***India:*** Ferrochelate; Logical; Tonoferon; ***Indon.:*** Champs C with Lysine; ***Ital.:*** Biocarnil†; Calciofix; ***Mex.:*** Corpotasin CL; ***Singapore:*** Champs C with Lysine; ***Spain:*** Euzymina Lisina I; Euzymina Lisina II; Malandil; Pranzo; ***USA:*** Klorvess.

Magnesium Fluoride
Фторид Магния

MgF_2 = 62.30.

CAS — 7783-40-6.

Profile
Magnesium fluoride is used as a fluoride supplement (see Sodium Fluoride, p.1962) for the prevention of dental caries. Magnesium fluoride is also used as a source of magnesium.

Homoeopathy. Magnesium fluoride has been used in homoeopathic medicines under the following names: Magnesia Fluorata; Magnesium Fluoratum; Magnesia Fluoricum.

Preparations
Proprietary Preparations (details are given in Part 3)
Multi-ingredient: ***Spain:*** Magnesium Pyre; Magnogene.

Maize Oil
Aceite de maíz; Corn Oil; Huile de Maïs; Kukoricamagolaj; Kukuřičný olej; Kukurūzų aliejus; Maïs, huile de; Maissiöljy; Majsolja; Maydis oleum; Ol. Mayd.; Olej kukurydziany; Oleum Maydis.

Pharmacopoeias. In *Chin.*, *Eur* (see p.vii), and *Jpn*. Also in *USNF*.
Ph. Eur. 6.2 (Maize Oil, Refined; Maydis Oleum Raffinatum). The refined fatty oil obtained from the seeds of *Zea mays*. A clear, light yellow or yellow oil. Practically insoluble in water and in alcohol; miscible with dichloromethane and with petroleum spirit (b.p.: 40° to 60°). Store at a temperature not exceeding 25°. Protect from light.
USNF 26 (Corn Oil). The refined fixed oil obtained from the embryos of *Zea mays* (Gramineae). A clear, light yellow, oily liquid having a faint characteristic odour. Slightly soluble in alcohol; miscible with chloroform, with ether, with petroleum spirit, and with benzene. Store in airtight containers at a temperature not exceeding 40°. Protect from light.

Profile
Maize oil is a fixed oil with a high content of unsaturated acids, and has been used to replace saturated acids in the diets of patients with familial hypercholesterolaemia. It is also used as an oily vehicle in pharmaceutical formulations.

Preparations
Proprietary Preparations (details are given in Part 3)
Pol.: Gal-Vit†.

Multi-ingredient: ***Fr.:*** Preservation; ***USA:*** Lipomul.

Malt Extract
Extractum Bynes; Malta, extracto de.

Profile
Malt extract contains 50% or more of maltose, with dextrin, glucose, and small amounts of other carbohydrates, and protein. It is prepared from malted grain of barley (*Hordeum distichon*, *H. vulgare*) or a mixture of this with not more than 33% of malted grain of wheat (*Triticum aestivum* or *T. turgidum*).

Malt extract has nutritive properties. It is chiefly used as a vehicle in preparations containing cod-liver oil (p.1935) and halibut-liver oil (p.1948). It is a useful flavouring agent for masking bitter tastes.

A product known as malt soup extract, obtained from barley grains, and containing 73% maltose with 12% other polymeric carbohydrates as well as small amounts of proteins, electrolytes, and vitamins, is sometimes used as a laxative.

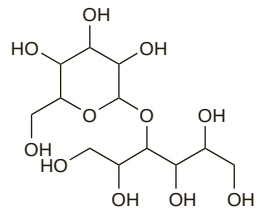
Preparations
Proprietary Preparations (details are given in Part 3)
Chile: Maltin; ***USA:*** Maltsupex.

Multi-ingredient: ***Fr.:*** Galactogil; ***S.Afr.:*** Cough Elixir.

Maltitol *(BAN)*
E965; Hydrogenated Maltose; D-Maltitol; Maltitoli; Maltitolis; Maltitolum. α-D-Glucopyranosyl-1,4-D-glucitol.

$C_{12}H_{24}O_{11}$ = 344.3.

CAS — 585-88-6.



Pharmacopoeias. In *Eur.* (see p.vii). Also in *USNF*.
Ph. Eur. 6.2 (Maltitol). A white or almost white, crystalline powder. Very soluble in water; practically insoluble in dehydrated alcohol.
USNF 26 (Maltitol). A white, crystalline powder. Very soluble in water; practically insoluble in dehydrated alcohol.

Maltitol Syrup
E965; Hydrogenated Glucose Syrup; Hydrogenated High Maltose-glucose Syrup; Liquid Maltitol; Maltitol ciekły; Maltitol, flytande; Maltitol, jarabe de; Maltitol liquide; Maltitol roztok; Maltitol Solution; Maltitoli, nestemäinen; Maltitolum liquidum; Maltitszirup; Skystasis maltitolis.

Pharmacopoeias. In *Eur.* (see p.vii). Also in *USNF*.
Ph. Eur. 6.2 (Maltitol, Liquid). An aqueous solution of a hydrogenated, part hydrolysed starch, containing not less than 68.0% w/w and not more than 85.0% w/w of anhydrous substance composed of a mixture of mainly D-maltitol with D-sorbitol and hydrogenated oligo- and polysaccharides. It contains not less than 50.0% w/w of D-maltitol and not more than 8.0% w/w of D-sorbitol, both calculated with reference to the anhydrous substance. A clear, colourless, syrupy liquid. Miscible with water and with glycerol.
USNF 26 (Maltitol Solution). A water solution containing, on the anhydrous basis, not less than 50.0% of D-maltitol (w/w) and not more than 8.0% of D-sorbitol (w/w).

Nomenclature. Hydrogenated glucose syrup is a generic term encompassing products of widely varying composition and it was concluded that such products containing up to 90% of maltitol should more properly be called maltitol syrup.[1] This was subsequently amended to include products containing up to 98% maltitol.[2] Preparations containing a minimum of 98% of maltitol were assigned the title maltitol.

1. FAO/WHO. Evaluation of certain food additives and contaminants: thirty-third report of the joint FAO/WHO expert committee on food additives. *WHO Tech Rep Ser 776* 1989.
2. FAO/WHO. Evaluation of certain food additives and contaminants: forty-first report of the joint FAO/WHO expert committee on food additives. *WHO Tech Rep Ser 837* 1993.

Profile
Maltitol and maltitol syrup are bulk sweeteners used in foods and pharmaceuticals; they are considered to be less cariogenic than sucrose. The ingestion of large quantities may produce flatulence and diarrhoea.

Maltodextrin
Maltodekstriini; Maltodekstrinas; Maltodextrina; Maltodextrine; Maltodextrinum.

CAS — 9050-36-6.

Pharmacopoeias. In *Eur.* (see p.vii). Also in *USNF*.
Ph. Eur. 6.2 (Maltodextrin). A mixture of glucose, disaccharides, and polysaccharides, obtained by the partial hydrolysis of starch. The degree of hydrolysis, expressed as dextrose equivalent (DE) is not more than 20 (nominal value). A white or almost white, slightly hygroscopic powder or granules. Freely soluble in water.
USNF 26 (Maltodextrin). A nonsweet, nutritive saccharide mixture of polymers that consists of D-glucose units with a dextrose equivalent of less than 20. It is prepared by the partial hydrolysis of food grade starch with suitable acids and/or enzymes. White, hygroscopic powder or granules. Freely soluble or readily dispersible in water; slightly soluble to insoluble in dehydrated alcohol. pH of a 20% solution in water is between 4.0 and 7.0. Store in airtight containers at a temperature not exceeding 30° and a relative humidity not exceeding 50%.

Profile
Maltodextrin, a glucose polymer (malto-oligosaccharide), is a source of carbohydrate often used in oral dietary supplements and tube feeding. It rapidly releases glucose in the gastrointestinal tract but because of the high average molecular weight of maltodextrin, solutions have a lower osmolarity than isocaloric solutions of glucose. Additionally, preparations based on maltodextrin and intended for dietary supplementation usually have a low electrolyte content and are free of other sugars such as fructose, galactose, lactose, and sucrose. These properties make such preparations suitable for dietary supplementation in a variety of diseases including certain gastrointestinal disorders where mal-