sodium chloride 0.9% or glucose 5%; the first 25 mg of iron is given over 15 minutes and if no adverse reactions occur during this time, the remaining portion of the infusion is given at a rate of not more than 100 mL in 30 minutes. In the USA, the injection may be given undiluted at a rate not exceeding 50 mg iron (1 mL) per minute; maximum daily doses are similar to those given for intramuscular injection.

Preparations

BP 2008: Iron Dextran Injection;
USP 31: Iron Dextran Injection.

Proprietary Preparations (details are given in Part 3)
Arg.: Fexiron; ***Belg.:*** Fercayl; ***Canad.:*** Dexiron; Infufer; ***Denm.:*** Cosmofer; ***Ger.:*** Cosmofer; ***Gr.:*** Cosmofer; ***Hong Kong:*** Cosmofer†; ***India:*** Imferon; ***Indon.:*** Hibiron; ***Irl.:*** Cosmofer; ***Mex.:*** Driken; Ferrocel; Ferroin†; Hidex; Irondex; ***Norw.:*** Cosmofer; ***Philipp.:*** Cosmofer; ***Port.:*** Cosmofer; ***Spain:*** Imferon†; ***Switz.:*** Ferrum Hausmann; ***Thai.:*** Cosmofer; ***Turk.:*** Cosmofer; ***UK:*** Cosmofer; ***USA:*** DexFerrum; INFeD; ***Venez.:*** Cosmofer.

Iron Polymaltose

Demir III Hidroksit Polimaltoz; Ferromaltose; Ferrum Polyisomaltose; Hierro polimaltosa.

Profile

Iron polymaltose is a complex of ferric hydroxide and isomaltose. It is used as a source of iron (p.1949) for iron-deficiency anaemia (p.1951). It is given orally in usual doses containing the equivalent of 100 mg of iron daily although up to 300 mg daily has been given in some countries. It is also given parenterally, the total dose being calculated and given by intravenous infusion or, preferably, as a series of intramuscular injections containing the equivalent of up to 200 mg of iron in a single day; injections are usually given only every few days. For further information relating to the parenteral use of iron, see Iron Dextran, p.1951.

Preparations

Proprietary Preparations (details are given in Part 3)
Arg.: Ferranin; Maltofer; Siderblut; Vitalix; ***Austral.:*** Ferrosig; Ferrum H; ***Austria:*** Ferrum Hausmann; ***Braz.:*** Noripurum; Ultrafer; ***Chile:*** Ferium; Maltofer; ***Cz.:*** Ferrum; Maltofer; ***Fin.:*** Maltofer; ***Fr.:*** Maltofer†; ***Ger.:*** Ferrum Hausmann; ***Gr.:*** Antianem; Dextrifer; Ferrobest; Ferrum Hausmann; Hemafer; Hydrofer-3; Veltifer; ***Hong Kong:*** Ferrum Hausmann; ***Hung.:*** Maltofer; ***India:*** Fericip; Mumfer; Phosfomin Iron; ***Indon.:*** Maltofer; ***Irl.:*** Ferrum; ***Israel:*** Ferripel; ***Ital.:*** Intrafer; ***Malaysia:*** Maltofer; Saferon; ***Mex.:*** Ferranina; ***NZ:*** Ferrosig; Ferrum H; ***Pol.:*** Ferrum Lek; ***Port.:*** Ferrum Hausmann; Maltofer; ***Rus.:*** Ferrum Lek (Феррум Лек); ***S.Afr.:*** Ferrimed; Ferrimed DS; ***Singapore:*** Ferrum Hausmann; ***Switz.:*** Maltofer; ***Turk.:*** Ferrum Hausmann; Maltofer; ***Venez.:*** Intafer; Maltofer.

Multi-ingredient: ***Arg.:*** Ferranin Complex; Hierro Dupofol; Isis Fe; Maltofer Fol†; Siderblut Folic; Tenvic; Vitalix Complex; ***Braz.:*** Noripurum Folico; Noripurum Vitaminado; ***Chile:*** Maltofer Fol; ***Cz.:*** Maltofer Fol; ***Gr.:*** Dextrifer-Fol; Ferrum Fol Hausmann; Hemafer fol; ***Hong Kong:*** Eurofer; ***Hung.:*** Maltofer Fol; ***India:*** Fericip; Hepofer; Mumfer-Z†; Mumfer†; ***Indon.:*** Feritrin; Maltofer Fol; ***Israel:*** Ferrifol; ***Malaysia:*** Maltofer; ***Mex.:*** Ferranina Complex; Ferranina Fol; Ironfol; ***Philipp.:*** Eurofer; ***Port.:*** Ferrum Fol; Maltoferfol; ***S.Afr.:*** Ferrimed; ***Singapore:*** Eurofer; Saferon†; ***Switz.:*** Maltofer Fol; ***Thai.:*** Eurofer; Orofer; ***Turk.:*** Ferrum Fort Hausmann; Maltofer Fol; ***Venez.:*** Intafer; Intaferfol; Maltoferfol.

Iron Sorbitol

Astra-1572; Demir Sorbitol; Hierro sorbitol; Iron Sorbitex *(USAN)*; Iron-Sorbitol-Citric Acid Complex.

CAS — 1338-16-5.
ATC Vet — QB03AC03.

Pharmacopoeias. *US* includes an injection.
USP 31 (Iron Sorbitex Injection). A sterile solution of a complex of iron, sorbitol, and citric acid that is stabilised with the aid of dextrin and an excess of sorbitol. pH 7.2 to 7.9.

Adverse Effects, Treatment, and Precautions

As for Iron Dextran, p.1951.

There may be severe systemic reactions; cardiac complications, such as complete AV block, ventricular tachycardia, and atrial or ventricular fibrillation, may be fatal. The urine of patients treated with iron sorbitol may become dark on standing.

Iron sorbitol should not be given intravenously. It should preferably be avoided in patients with pre-existing cardiac abnormalities.

Effects on the heart. A description of adverse events in 3 patients with the malabsorption syndrome treated with intramuscular injections of iron sorbitol.[1] Two patients died; in one, findings were consistent with anaphylaxis but in the other cardiac toxicity was considered to be due to a direct effect. In the third patient direct cardiac toxicity was also implicated. In another report,[2] a patient developed cardiac arrhythmia after his seventh injection of iron sorbitol. He was found to have a low serum concentration of alpha-tocopherol, supposed by the authors to be caused by the patient's malabsorption syndrome. This had apparently predisposed the patient to arrhythmia by contributing to myocardial cell sensitivity to lipid peroxidation, which is catalysed by ferrous ions. Insufficient alpha-tocopherol to scavenge the free radicals generated by the iron could also have led to loss of myocardial fatty acids, thereby disturbing membrane function. It was suggested that iron sorbitol was a less stable form of iron than iron dextran, and should be given with extreme caution to patients with malabsorption and low levels of alpha-tocopherol.

1. Karhunen P, *et al*. Reaction to iron sorbitol injection in three cases of malabsorption. *BMJ* 1970; **2:** 521–2.
2. Lindvall S, *et al*. Alpha-tocopherol and cardiac toxicity of iron. *Scand J Haematol* 1980; **25:** 331–8.

Interactions

As for Iron Dextran, p.1952.

Pharmacokinetics

About 66% of iron sorbitol is absorbed within 3 hours of intramuscular injection, most of it directly into the blood circulation, and some via the lymphatic system. Almost all is absorbed within about 10 days. Clearance of iron sorbitol from the plasma is rapid, and is mainly via the reticuloendothelial system, as described for Iron Dextran, p.1952.

Uses and Administration

Iron sorbitol should be used only in the treatment of proven iron-deficiency anaemia (p.1951) where oral therapy is ineffective or impracticable.

It is given by deep intramuscular injection into the upper outer quadrant of the buttock; to prevent leakage along the injection track, the subcutaneous tissue is drawn to one side before the needle is inserted.

Total dosage is calculated according to body-weight and the haemoglobin concentration of the blood, and tables are usually provided with iron sorbitol injections for this purpose. The recommended single dose is the equivalent of 1.5 mg/kg of iron up to a maximum of 100 mg daily; these doses are then given daily or every other day until the required haemoglobin concentration has been achieved. Iron sorbitol is not recommended in children weighing under 3 kg.

Iron sorbitol should not be given intravenously.

Preparations

USP 31: Iron Sorbitex Injection.

Proprietary Preparations (details are given in Part 3)
Arg.: Yectafer; ***Canad.:*** Jectofer†; ***Ger.:*** Jectofer†; ***India:*** Jectocos; ***Irl.:*** Jectofer†; ***Norw.:*** Jectofer†; ***Turk.:*** Jectofer.

Multi-ingredient: ***Arg.:*** Yectafer Complex; ***India:*** Jectocos Plus.

Iron Succinyl-Protein Complex

Demir III Protein Süksinat; Ferro Proteinsuccinilato; Hierro succinil-proteína, complejo de; Iron Proteinsuccinylate; ITF-282; Proteinsuccilinato de hierro.

CAS — 93615-44-2.
ATC — B03AB09.
ATC Vet — QB03AB09.

Profile

Iron succinyl-protein complex is a source of iron (p.1949) used for iron-deficiency anaemia (p.1951). It is given orally in doses of up to 1.6 g daily (equivalent to up to 80 mg of iron daily).

◊ References.

1. Köpcke W, Sauerland MC. Meta-analysis of efficacy and tolerability data on iron proteinsuccinylate in patients with iron deficiency anemia of different severity. *Arzneimittelforschung* 1995; **45:** 1211–16.

Preparations

Proprietary Preparations (details are given in Part 3)
Arg.: Ferplex; ***Braz.:*** Fisiofer†; ***Chile:*** Fisiofer; Legofer; ***Cz.:*** Ferplex; ***Gr.:*** Fysiofer; Legofer; ***Ital.:*** Ferlatum; Ferplex; Ferremon†; Folinemic Ferro†; Legofer†; Pemexin; Proteoferrina; Rekord Ferro; ***Mex.:*** Ferxal; ***Pol.:*** Ferplex; ***Port.:*** Fervit; Fetrival; Legofer; ***Rus.:*** Ferlatum (Ферлатум); ***Spain:*** Ferplex; Ferrocur; Lactoferrina; ***Turk.:*** Ferplex.

Multi-ingredient: ***Gr.:*** Fysiofol; ***Ital.:*** Ferrofolin; ***Turk.:*** Ferplex Fol.

Iron Sucrose *(BAN, USAN)*

Demir Sükroz; Eisenzucker; Ferri oxidum saccharatum; Ferric Hydroxide Sucrose; Ferric Oxide, Saccharated; Ferrique (oxyde) sucré; Ferrum Oxydatum Saccharatum; Hierro sacarosa; Iron (III) hydroxide-sucrose complex; Iron Saccharate; Oxyde de Fer Sucré; Saccharated ferric oxide; Saccharated Iron Oxide; XI-921.

CAS — 8047-67-4.
ATC — B03AB02; B03AC02.
ATC Vet — QB03AB02; QB03AC02.

Pharmacopoeias. In *Swiss*.
US includes an injection.
USP 31 (Iron Sucrose Injection). A sterile, colloidal solution of ferric hydroxide in complex with sucrose in water for injection. Sodium hydroxide may be added to adjust the pH. It contains no antimicrobial agent, chelating agent, dextran, gluconate, or other added substances. pH 10.5 to 11.1 at 20°. It is intended for intravenous use only. When given by intravenous infusion, it should be diluted with 0.9% sodium chloride injection to a concentration of 0.5 to 2.0 mg of elemental iron/mL. Do not allow to freeze.

Adverse Effects, Treatment, and Precautions

For parenteral iron, see Iron Dextran, p.1951. Iron sucrose injection is strongly alkaline and must not be given subcutaneously or intramuscularly. UK (but not US) licensed drug information contra-indicates its use in patients with a history of asthma, eczema, anaphylaxis, or other allergic disorders.

Effects on the blood. For a report of thrombocytopenia associated with iron sucrose, see under Iron Dextran, p.1952.

Hypersensitivity. For a discussion of whether iron sucrose may be a safer alternative to iron dextran, see p.1952.

Pharmacokinetics

Iron sucrose is rapidly cleared from the plasma after intravenous injection with a terminal half-life of about 6 hours. A competitive exchange of iron takes place from the iron sucrose complex to the iron-binding protein transferrin. About 5% of a dose is eliminated via the kidneys in the first 4 hours after a dose.

Uses and Administration

Iron sucrose is used as a source of iron (p.1949) for iron-deficiency anaemia (p.1951). It is given when oral iron therapy is ineffective or impractical, by slow intravenous injection, or intravenous infusion; when used in haemodialysis patients, it may be given into the venous limb of the dialyser. The dose is calculated according to body-weight and iron deficit. In the UK the cumulative dose is given in single doses of 100 mg of iron not more than three times weekly; if rapid delivery is required, the dose may be increased up to 200 mg not more than three times weekly. The dose may be given undiluted at a rate of 20 mg/minute, after a test dose of 20 mg of iron has been given over 1 to 2 minutes. Alternatively, 100 mg is diluted in a maximum of 100 mL of sodium chloride 0.9% and the first 25 mg given as a test dose over 15 minutes; the remaining portion is given at a rate not exceeding 50 mL per 15 minutes.

In the USA, a similar dose is given for haemodialysis patients receiving supplemental erythropoietin therapy, to a total cumulative dose of 1 g. For peritoneal dialysis patients on erythropoietin, two infusions of 300 mg over 1.5 hours are given 14 days apart, followed by an infusion of 400 mg over 2.5 hours 14 days later. The doses are diluted in a maximum of 250 mL of sodium chloride 0.9%. For patients not on dialysis, a total cumulative dose of 1 g is given over a 14-day period, as a 200 mg slow undiluted intravenous injection over 2 to 5 minutes on 5 separate occasions within this time. Iron sucrose has also been given orally.

Anaemia of chronic renal failure. References.

1. Charytan C, *et al*. Efficacy and safety of iron sucrose for iron deficiency in patients with dialysis-associated anemia: North American clinical trial. *Am J Kidney Dis* 2001; **37:** 300–7.
2. Stoves J, *et al*. A randomized study of oral vs intravenous iron supplementation in patients with progressive renal insufficiency treated with erythropoietin. *Nephrol Dial Transplant* 2001; **16:** 967–74.
3. Chandler G, *et al*. Intravenous iron sucrose: establishing a safe dose. *Am J Kidney Dis* 2001; **38:** 988–91.
4. Blaustein DA, *et al*. The safety and efficacy of an accelerated iron sucrose dosing regimen in patients with chronic kidney disease. *Kidney Int* 2003; (suppl): S72–S77.
5. Charytan C, *et al*. Safety of iron sucrose in hemodialysis patients intolerant to other parenteral iron products. *Nephron Clin Pract* 2004; **96:** 63–6.
6. Leijn E, *et al*. Intravenous iron supplementation in children on hemodialysis. *J Nephrol* 2004; **17:** 423–6.
7. Aronoff GR, *et al*. Iron sucrose in hemodialysis patients: safety of replacement and maintenance regimens. *Kidney Int* 2004; **66:** 1193–8.
8. Van Wyck DB, *et al*. The United States Iron Sucrose (Venofer) Clinical Trials Group. A randomized, controlled trial comparing IV iron sucrose to oral iron in anemic patients with nondialysis-dependent CKD. *Kidney Int* 2005; **68:** 2846–56.
9. Hollands JM, *et al*. Safety of high-dose iron sucrose infusion in hospitalized patients with chronic kidney disease. *Am J Health-Syst Pharm* 2006; **63:** 731–4.

Preparations

USP 31: Iron Sucrose Injection.

Proprietary Preparations (details are given in Part 3)
Arg.: Energavit; Ferricrine; Sucrox; Venofer; ***Austral.:*** Venofer; ***Belg.:*** Venofer; ***Canad.:*** Venofer; ***Chile:*** Rafofer; Venofer; ***Cz.:*** Ferrologic; Ferrum; Venofer; ***Denm.:*** Venofer; ***Fin.:*** Venofer; ***Fr.:*** Venofer; ***Ger.:*** FERROinfant Neu†; Venofer; ***Gr.:*** Anemifer; Felix; Ferroprol; Ferrovin; Venofer; ***Hong Kong:*** Venofer; ***Hung.:*** Venofer; ***Indon.:*** Venofer; ***Israel:*** Venofer; ***Ital.:***

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†.

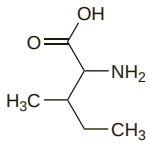
Isoleucine *(USAN, rINN)*

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.

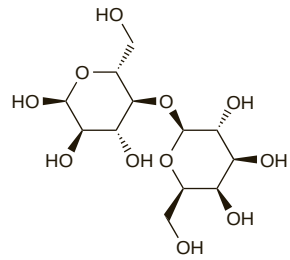
Metabolism. Isomalt is partly metabolised in the small intestine to glucose, mannitol, and sorbitol and the remaining isomalt is completely metabolised by the flora of the large intestine.[1] The Australian manufacturers have commented that the hydrolysis and absorption is minimal and does not significantly 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.

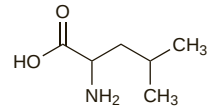
Leucine *(USAN, rINN)*

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.

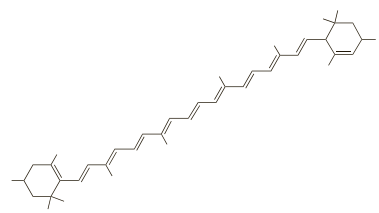
Lutein

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.