

to be adequate.¹ Similarly, in the USA a recommended dietary allowance has not been published but an adequate intake for adults was believed to be 5 mg daily, increased to 6 mg in pregnancy and 7 mg during lactation.²

- 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.
- Standing Committee on the Scientific Evaluation of Dietary Reference Intakes of the Food and Nutrition Board. *Dietary Reference Intakes for thiamin, riboflavin, niacin, vitamin B₆, folate, vitamin B₁₂, pantothenic acid, biotin, and choline*. Washington, DC: National Academy Press, 2000. Also available at: <http://www.nap.edu/openbook.php?isbn=0309065542> (accessed 21/07/08)

Uses and Administration

Pantothenic acid is traditionally considered to be a vitamin B substance. It is a component of coenzyme A which is essential in the metabolism of carbohydrate, fat, and protein.

Deficiency of pantothenic acid is unlikely in man because of its widespread distribution in food.

Pantothenic acid has no accepted therapeutic uses in human medicine, though it has been given by mouth as a nutritional supplement, often as the calcium salt and usually with other vitamins of the B group.

Preparations

USP 31: Calcium Pantothenate Tablets.

Proprietary Preparations (details are given in Part 3)

Arg.: Cidemex; **Austral.:** Pantonate; **Ger.:** Kerato Bicorn; **Mex.:** Span Plex; **Rus.:** Zorex (Зофек); **Switz.:** Pantothen.

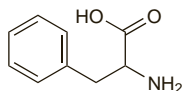
Multi-ingredient: Arg.: Bifena; Cellskinlab Hydragel B5; Culuflex H; Guarana Diates; Megaplus; Valeriana Relax Diates; **Austral.:** Bioglan Zn-A-C; Hair and Skin Formula; **Austria:** Lenuval; **Belg.:** Sili-Met-San; **Braz.:** Gaba; Pantevit; Varizol; **Chile:** Foltene Research Anticaspas; Hydrating B5 Gel; Modane; **Fr.:** Modane; **Ger.:** Azupanthenol; Carotin; Pantovigar N; Potsilo N; Regepithel; **Hong Kong:** Regepithel; **India:** Sioneuron; **Indon.:** Proimbus; **Ital.:** Esaglut; Nuleron; Silisan; Vitecaf; **Malaysia:** Vitamin C-500 YSP; **Mex.:** Espaven; Modaton; **Spain:** Calcio 20 Complex; Hubergrip; Lacerdermol; Lupidon; Pantenil; Pulmofasa; Tri Hachemina; **Switz.:** Cortifluid N; Decsept N; Sili-Met-San.

Phenylalanine (USAN, rINN)

α -Aminohydrocinnamic Acid; F; Fenilalanin; Fenilalanina; Fenilalaninas; Fenyilalanin; Fenyloalanina; Fenyilalanini; Phe; Phénylalanine; L-Phénylalanine; Phenylalaninum. L-2-Amino-3-phenylpropionic acid.

Фенилаланин

$C_9H_9NO_2 = 165.2$.
CAS — 63-91-2.



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

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

USP 31 (Phenylalanine). White, odourless crystals. Sparingly soluble in water; very slightly soluble in alcohol, in methyl alcohol, and in dilute mineral acids. pH of a 1% solution in water is between 5.4 and 6.0.

Profile

Phenylalanine is an aromatic amino acid that is an essential constituent of the diet. It is used as a dietary supplement.

Phenylalanine intake should be restricted in patients with phenylketonuria (see Amino Acid Metabolic Disorders, p.1922).

Vitiligo. There is no totally effective treatment for vitiligo (localised hypopigmentation, p.1582). Oral or topical photochemotherapy with psoralens is generally considered to be the best available treatment, but experimental therapy includes UVA phototherapy with phenylalanine. Use of phenylalanine in oral doses of up to 100 mg/kg with UVA/sunlight led to beneficial results in more than 90% of 200 patients with vitiligo.¹ Greatest benefit was noted in early disease, but prolonged use still induced repigmentation in long-standing cases. Repigmentation occurred mainly in areas rich in follicles. Such therapy is contraindicated in phenylketonuria and in pregnancy.

Similarly a further open study reported responses in 94 of 149 patients receiving 50 to 100 mg/kg daily of phenylalanine plus twice weekly UVA treatment.² However, only 22% of responders had repigmentation in more than 60% of the affected area. Higher doses did not seem to be more effective than 50 mg/kg daily. Another group reported on 6 years of experience of treatment of vitiligo using 50 or 100 mg/kg daily of phenylalanine, with application of 10% phenylalanine gel and daily sun exposure.³ Although not ideal, they considered the treatment useful, especially for its ability to rapidly repigment the face. The same group performed an open study, adding topical 0.025% clobeta-

sol propionate, and ultraviolet exposure during autumn and winter; 65.5% of patients achieved 100% repigmentation on the face.⁴

- Cormane RH, *et al.* Treatment of vitiligo with α -phenylalanine and light. *Br J Dermatol* 1986; **115**: 587.
- Siddiqui AH, *et al.* L-Phenylalanine and UVA irradiation in the treatment of vitiligo. *Dermatology* 1994; **188**: 215–18.
- Camacho F, Mazuecos J. Treatment of vitiligo with oral and topical phenylalanine: 6 years of experience. *Arch Dermatol* 1999; **135**: 216–17.
- Camacho F, Mazuecos J. Oral and topical L-phenylalanine, clobetasol propionate, and UVA/sunlight - a new study for the treatment of vitiligo. *J Drugs Dermatol* 2002; **2**: 127–31.

Preparations

Proprietary Preparations (details are given in Part 3)

Multi-ingredient: Arg.: KLB6 Fruit Diet; **Fr.:** Revitalose.

Polysaccharide-Iron Complex

Polisacárido hierro, complejo.

Profile

Polysaccharide-iron complex is used as a source of iron (p.1949) for iron-deficiency anaemia (p.1951). It is given orally in doses containing the equivalent of up to 300 mg of iron daily.

Preparations

Proprietary Preparations (details are given in Part 3)

Belg.: Femcure; **Chile:** Niferex†; **Hong Kong:** Niferex; **Norw.:** Niferex; **Pol.:** Venofor; **UK:** Niferex; **USA:** Fe-Tinic; Ferrex; Ferrex Plus; Hytinitic; Niferex; Nu-Iron†; Poly-Iron.

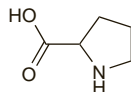
Multi-ingredient: USA: Fe-Tinic Forte; Ferrex Forte; Ferrex Forte Plus†; Ferrex PC; Hemocyte-F; Niferex Forte; Nu-Iron V; Poly-Iron Forte; Tandem.

Proline (USAN, rINN)

P; Pro; Prolini; Prolin; Prolina; Prolinas; L-Proline; Prolinum. L-Pyrrolidine-2-carboxylic acid.

ПРОЛИН

$C_5H_9NO_2 = 115.1$.
CAS — 147-85-3.



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

Ph. Eur. 6.2 (Proline). A white or almost white, crystalline powder or colourless crystals. Very soluble in water; freely soluble in alcohol. Protect from light.

USP 31 (Proline). White, odourless crystals. Freely soluble in water and in dehydrated alcohol; insoluble in butyl alcohol, in ether, and in isopropyl alcohol.

Profile

Proline is a cyclic non-essential amino acid. It is used as a dietary supplement.

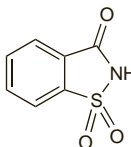
Preparations

Proprietary Preparations (details are given in Part 3)

Multi-ingredient: Port.: Creme Laser Hidrante.

Saccharin

Benzoic Acid Sulphimide; Benzoic Sulfimide; Benzosulphimide; E954; Gluside; Sacarina; Sacarina; Saccharine; Saccharinum; Saccharin; Saccharinas; Sacharyna; Sackarin; Sakkarini; o-Sulfobenzimid; Szacharin; Zaharina. 1,2-Benzisothiazolin-3-one 1,1-dioxide. $C_7H_5NO_3S = 183.2$.
CAS — 81-07-2.



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

Ph. Eur. 6.2 (Saccharin). A white or almost white, crystalline powder or colourless crystals. Slightly soluble in cold water; sparingly soluble in boiling water and in alcohol. It dissolves in dilute solutions of alkali hydroxides and carbonates. A saturated solution, prepared without heating, is acid to litmus.

USNF 26 (Saccharin). White crystals or white, crystalline powder. Is odourless or has a faint, aromatic odour. In dilute solutions, it is intensely sweet. Soluble 1 in 290 of water, 1 in 25 of boiling water, and 1 in 31 of alcohol; slightly soluble in chloroform and in ether; is readily dissolved by dilute solutions of

ammonia, by solutions of alkali hydroxides, and by solutions of alkali carbonates with the evolution of carbon dioxide. Its solutions are acid to litmus.

Saccharin Calcium

Calcium Benzosulphimide; Calcium Saccharin; E954; Sacarina cálcica; Saccharine calcique; Saccharinum calcicum. $C_{14}H_9CaN_2O_4S_2 \cdot 3H_2O = 467.5$.
CAS — 6485-34-3 (anhydrous saccharin calcium); 6381-91-5 (hydrated saccharin calcium).

Pharmacopoeias. In US.

USP 31 (Saccharin Calcium). White crystals or white, crystalline powder. Is odourless, or has a faint, aromatic odour, and has an intensely sweet taste, even in dilute solutions. Its dilute solution is about 300 times as sweet as sucrose. Soluble 1 in 2.6 of water and 1 in 4.7 of alcohol.

Saccharin Potassium

E954; Potassium Benzosulphimide; Potassium Saccharin.

$C_7H_5NO_3SK = 222.3$.

CAS — 10332-51-1.

Saccharin Sodium

E954; Sacarina sódica; Saccharin Sod.; Saccharine sodique; Saccharinnatrium; Saccharinum natrium; Saccharoidum Natrium; Saccharin sodná sůl; Sacharino natrio druska; Sacharyna sodowa; Sackarinatrium; Sakkarinatrium; Sodium Benzosulphimide; Sodium Saccharin; Soluble Gluside; Soluble Saccharin; Szacharin-nátrium.

$C_7H_4NNaO_3S = 205.2$.

CAS — 128-44-9 (anhydrous saccharin sodium); 6155-57-3 (saccharin sodium dihydrate).

Pharmacopoeias. In *Chin.*, *Eur.* (see p.vii), *Int.*, *Jpn.* and *US*. Some pharmacopoeias specify the dihydrate but it may contain a variable quantity of water as a result of efflorescence.

Ph. Eur. 6.2 (Saccharin Sodium). A white or almost white, crystalline powder or colourless crystals. It may contain a variable quantity of water. Efflorescent in dry air. Freely soluble in water; sparingly soluble in alcohol. Store in airtight containers.

USP 31 (Saccharin Sodium). White crystals or white, crystalline powder. Is odourless, or has a faint, aromatic odour, and has an intensely sweet taste, even in dilute solutions. Its dilute solution is about 300 times as sweet as sucrose. When in powdered form, it usually contains about one-third the theoretical amount of water of hydration as a result of efflorescence. Soluble 1 in 1.5 of water and 1 in 50 of alcohol.

Adverse Effects

There have been rare reports of hypersensitivity and photosensitivity reactions with saccharin.

Saccharin-associated bladder tumours in *rats* given high doses have been the cause of much concern and investigation. However, it is now generally accepted that these findings are not relevant to the use of saccharin as a sweetener in man.

Effects on the liver. Elevated liver enzyme values in an elderly woman followed use of two different medications sweetened with saccharin sodium.¹ Findings resolved on stopping all preparations containing saccharin, and recurred on challenge with a small amount of saccharin sodium.

1. Negro F, *et al.* Hepatotoxicity of saccharin. *N Engl J Med* 1994; **331**: 134–5.

Pharmacokinetics

Saccharin is readily absorbed from the gastrointestinal tract. It is almost all excreted unchanged in the urine within 24 to 48 hours.

Uses and Administration

Saccharin and its salts are intense sweeteners, a dilute solution having about 300 times the sweetening power of sucrose. They are used in pharmaceuticals and in foods and beverages and are heat stable. They have no food value. The salts are more often used than saccharin itself as they are considered to be more palatable.

Preparations

USP 31: Saccharin Sodium Oral Solution; Saccharin Sodium Tablets.

Proprietary Preparations (details are given in Part 3)

Chile: Dul-Suc; Sukar-Sin; **Fr.:** Sucredulcor†; **NZ:** Sactabs; **Turk.:** Hermesetas; **Venez.:** Hermesetas.

Multi-ingredient: Arg.: Chuker; Rondo; Semble; Sucaryl; Suimel; **Austral.:** Sucaryl; **Braz.:** Finn Cristal; **Chile:** Sucaryl†; Sukar-Sin; **Fr.:** Sucaryl; **Israel:** Sucrin; **Ital.:** Diet Sucaryl; **NZ:** Sucaryl; **Port.:** Dulcerif†; **Rus.:** Zuckil (Цюкки); **Turk.:** Dolce.

Safflower Oil

Aceite de alazor; Aceite de cártamo; Carthame (huile de) raffinée; Carthami oleum raffinum; Dymnijn aliejus, rafinuotas; Safflorolja, raffinerad; Saffloröljy, puhdistettu; Světlíkový olej čistěný.

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

Chin., *Eur.* (see p.vii), and *Jpn* include Safflower, the flower of *Carthamus tinctorius*.

Ph. Eur. 6.2 (Safflower Flower; Carthami Flos). Dried flower of