

suprine also produces positive inotropic and chronotropic effects.

Isosuprine hydrochloride has been used to arrest premature labour (p.2003), but drugs with a more selective action are now preferred. It has also been given in the treatment of cerebral and peripheral vascular disease.

For use as a vasodilator, isosuprine hydrochloride is given by mouth in doses of 10 to 20 mg 3 or 4 times daily.

To arrest premature labour, isosuprine hydrochloride is given initially by intravenous infusion in doses of 200 to 500 micrograms/minute, adjusted according to the patient's response, until control is achieved. It is now common practice to give beta agonists by syringe pump when using them to delay premature labour. Maternal blood pressure and hydration, and maternal and fetal heart rates should be monitored during the infusion. Once labour has been arrested intramuscular injections of 10 mg are given every 3 to 8 hours for several days. Prophylaxis may be continued by mouth with 30 to 90 mg daily in divided doses.

The resinate has also been used similarly.

## Preparations

**USP 31:** Isosuprine Hydrochloride Injection; Isosuprine Hydrochloride Tablets.

### Proprietary Preparations (details are given in Part 3)

**Arg.:** Duvadilan; Fadaespaasmol†; Isodilan; Isotenk; Samaruc; Uterine; **Austria:** Xuprin; **Braz.:** Inibina; **Gr.:** Duvadilan†; **India:** Duvadilan; **Indon.:** Duvadilan; Hystolan; **Israel:** Vasolan†; **Ital.:** Vasosuprina Ifi; **Mex.:** Vadosilan; **Philipp.:** Duvadilan; **Isloxian; Port.:** Dilum; **Thai:** Duvadilan†; **USA:** Vasodilan; Voxsuprine; **Venez.:** Duvadilan.

## Ivy

Břečťanový list (ivy leaf); Efeu; Gebenij lapai (ivy leaf); Hederae folium (ivy leaf); Herba Hederae Helicis; Lierre, feuille de (ivy leaf); Lierre Grimpan; Muratinlehti (ivy leaf); Murggröneblad (ivy leaf).

**Pharmacopoeias.** *Eur.* (see p.vii) includes the leaf and also a form for homeopathic preparations.

**Ph. Eur. 6.2** (Ivy Leaf; Hederae Folium). The whole or cut, dried leaves of *Hedera helix*, collected in the spring. It contains a minimum of 3% of hederacoside C (C<sub>39</sub>H<sub>56</sub>O<sub>26</sub> = 1221.4), calculated with reference to the dried drug. Protect from light.

**Ph. Eur. 6.2** (Hedera Helix for Homeopathic Preparations; Hedera Helix ad Praeparationes Homeopathicas). The fresh, young, fully developed but not yet lignified branch of *Hedera helix*, harvested immediately before or at the beginning of flowering. Protect from light.

### Profile

The dried leaves of ivy, *Hedera helix* (Araliaceae), contain saponins, and extracts are reported to have expectorant and spasmolytic actions. Ivy leaf is used for catarrh and chronic inflammation of the respiratory tract. It has also been applied externally.

Fresh ivy leaves can cause allergic contact dermatitis.

**Homeopathy.** Ivy has been used in homeopathic medicines under the following names: Hedera helix; Hed. hel.

### Reviews.

- Hofmann D, *et al.* Efficacy of dry extract of ivy leaves in children with bronchial asthma—a review of randomized controlled trials. *Phytomedicine* 2003; **10**: 213–220.

## Preparations

### Proprietary Preparations (details are given in Part 3)

**Arg.:** Athos; Cedric; **Austria:** Prospan; Sedo-Efeu; **Braz.:** Abrilar; **Chile:** Aeromed; Hedilar; **Cz.:** Hedelix; Helixir; Prospan; **Fr.:** Activox Lierre; Prospan; **Ger.:** Bronchilon; Bronchoforton; Bronchostad Hustenlöser; Cepapulmon mono†; Efeu; Gallith; Hedelix; Prospan; Sedotussin Efeu; Sinuc; Tuma; **Gr.:** Prospan; **Ital.:** Vertuss; **Malaysia:** Prospan; **Mex.:** Panoto-S; **Pol.:** Bronchopect; Hedelix; Hederasal; Hederoin; Helical; Prospan; **Singapore:** Prospan; **Spain:** Arkotux; **Switz.:** Comprimes contre la toux†; DemoPectol Junior; Prospan; Pumonol eco natura; **Venez.:** Prospan.

**Multi-ingredient:** **Arg.:** Celu-Atlas; Expectosan Hierbas y Miel; Garcinol Max†; Nio Marine; Snell Patch; Vansedan Gel; **Austral.:** Asa Tones; **Austria:** Bronchipret; **Fr.:** Promincil†; **Ger.:** Bronchipret; Muc-Sabona†; Naranopect P; Tussiflorin forte†; **Hung.:** Bronchipret; **Indon.:** Bronchipret; **Ital.:** Demoprolin†; Flebolider; Galatux Hederix; **Pol.:** Api-Helix; Hedelicum; Pini-Helix; **Rus.:** Bronchipret (Бронхипрет); Insti (Инсти); **Spain:** H Tussan; **Switz.:** Bronchofluid N†; Bronchoson Nouvelle formule†; Demo Elixir pectoral N; DemoPectol; Dragees S contre la toux†; Drosinulaf; Foraf†; Hedex; Kernosan Elixir; LiberoL Dragees contre la toux†; LiberoL Sirop contre la toux†; Pastilles pectorales Demo N; **Thai.:** Solvopret.

## Jamaica Dogwood

Fish Poison Bark; Piscidia.

### Profile

Jamaica dogwood, the root bark of *Piscidia erythrina* (*P. piscipula*; *Ichthyomethia piscipula*) (Leguminosae), has analgesic, antispasmodic, and sedative properties. It is mainly used for insomnia due to neuralgia or nervous tension. The bark and twigs of Jamaica dogwood have been used as a fish poison.

## Preparations

### Proprietary Preparations (details are given in Part 3)

**Multi-ingredient:** **Fr.:** Jouvence de l'Abbe Soury; Schoum; **Ital.:** Sedatol; Soluzione Schoum; **Spain:** Elucion Schoum; **UK:** Anased; HRI Calm Life; Nodoff; Slumber; **Venez.:** Femendol.

## Java Tea

Arbatinių inkstažolių lapai; Jaavalainen tee, Intialainen munuaistee; Jávai vesetealevél; Javate; Orthosiphon; Orthosiphonblätter; Orthosiphonis folium; Ortosifón; Trubkovcový list.

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

**Ph. Eur. 6.2** (Java Tea). The fragmented, dried leaves and tops of stems of *Orthosiphon stamineus* (*O. aristatus*; *O. spicatus*). Protect from light.

### Profile

Java tea is used in herbal medicine mainly for the treatment of urinary-tract disorders.

## Preparations

### Proprietary Preparations (details are given in Part 3)

**Fr.:** Urosiphon; **Ger.:** Ardeynephron; Carito mono; Diurevit Mono; Nephronorm med; Orthosiphonblätter Indischer Nierentee; Repha Orphon.

**Multi-ingredient:** **Austria:** Solubitat; **Fr.:** Dellova†; Promincil†; Tealine†; **Ger.:** Aqualibra; BioCyst; Canephron novo†; Dr. Scheffler Bergischer Krauttee Blasen- und Nierentee; Harntee 400 N; Harntee STADA; Harntee-Steiner; Heumann Blasen- und Nierentee Solubitat S†; Hevert-Blasen-Nieren-Tee N; Heveberberol-Tee; Nephro-Pasc†; Nephronorm med†; Nephropur tri†; Nephruhin-N†; Nierentee 2000†; Nieron Blasen- und Nieren-Tee VII†; Presselin Artenen K 5 P†; Presselin Nieren-Blasen K 3†; Urodl phyto†; **Indon.:** Renax; **Ital.:** Lipaven; **Pol.:** Ginjal; **Spain:** Lepisor†; Urisor†; **Switz.:** Bilifuge; Demonatur Dragees pour les reins et la vessie; Phytomed Nephro†; Prosta-Caps Chassot N; Tisane pour les reins et la vessie.

## Jin Bu Huan

### Profile

Jin bu huan is a traditional Chinese remedy used as a sedative and analgesic and variously stated to contain *Lycopodium serratum* or *Polygala chinensis*. Adverse effects including CNS depression and acute hepatotoxicity have been attributed to its alkaloidal content of L-tetrahydrocypalmatine.

**Adverse effects.** Acute hepatitis has been reported in 7 previously healthy patients after taking jin bu huan; symptoms occurred again in 2 after re-use.<sup>1</sup> It was noted that the content of plant material did not seem to correspond to the labelled species. Hepatitis and extreme fatigue have also been reported in 3 adults after taking jin bu huan for periods ranging from 6 days to 6 months.<sup>2</sup>

Accidental ingestion of jin bu huan by 3 children<sup>2</sup> produced profound lethargy and muscle weakness. Two of the children also developed respiratory depression and bradycardia.

- Woolf GM, *et al.* Acute hepatitis associated with the Chinese herbal product jin bu huan. *Ann Intern Med* 1994; **121**: 729–35.
- Horowitz RS, *et al.* The clinical spectrum of jin bu huan toxicity. *Arch Intern Med* 1996; **156**: 899–903.

## Juniper

Baccae Juniperi; Boróka tobozbugyó; Enbär; Genièvre; Juniper pseudo-fructus; Jalovcový plod; Juniper Berry; Juniper Fruit; Juniperi Fructus; Juniperi Galbulus; Juniperi Pseudo-fructus; Kadagiy vaisiai; Katajanmarja; Szyszkojagoda jatowca; Wacholderbeeren; Zimbrow.

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

**Ph. Eur. 6.2** (Juniper). The dried ripe cone berry of *Juniperus communis*. It contains not less than 1% v/v of essential oil, calculated with reference to the anhydrous drug. It has a strongly aromatic odour, especially if crushed. Protect from light.

### Profile

Juniper is the source of juniper oil (below). It has carminative, diuretic, antiseptic, and anti-inflammatory properties. It is used in herbal medicine and as a flavour in gin.

**Homeopathy.** Juniper has been used in homeopathic medicines under the following names: Juniperus communis; Juniperus communis sicc.; Juniperus communis e fructibus siccat; Junip. c.

## Preparations

### Proprietary Preparations (details are given in Part 3)

**Cz.:** Plod jalovce†.

**Multi-ingredient:** **Arg.:** Water Pill c Potasio†; **Austral.:** Arthritic Pain Herbal Formula I; Lifesystem Herbal Formula I Arthritic Aid†; Profluid†; Protomp†; **Austria:** Manazeller; St Bonifatius-Tee; **Braz.:** Pilulas De Witt†; **Canada:** Herbal Diuretic; Herbal Laxative plus Yogurt; **Cz.:** Abfuhr-Heilkräutertee†; **Fr.:** Depuratum; Mediflor Tisane Antirhumatismale No 2; **Ger.:** Amara-Tropfen; Gastrol S†; Junisana†; Presselin Stoffwechsel-Tee Hapeka 225 N†; **Ital.:** Broncosedina; **Pol.:** Cholesol; **S.Afr.:** Amara; **Switz.:** Heparfellen; Kernosan Heidelberger Poudre; Phytomed Nephro†; Tisane pour les reins et la vessie; **UK:** Backache; Watershed.

## Juniper Oil

Borókaolaj; Enbärsolja; Enebro, aceite esencial de; Essence de Genièvre; Genièvre, huile essentielle de; Juniperi aetheroleum; Jalovcová silice; Juniper Berry Oil; Juniperi Aetheroleum; Juniperi Etheroleum; Kadagiy vaisių eterinis aliejus; Katajanmarjaöljy; Oleum Juniperi; Wacholderöl.

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

**Ph. Eur. 6.2** (Juniper Oil). The essential oil obtained by steam distillation from the ripe, non-fermented berry cones of *Juniperus communis*. A suitable antioxidant may be added. A mobile, colourless to yellowish liquid with a characteristic odour. Store in well-filled airtight containers at a temperature not exceeding 25°. Protect from light.

### Profile

Juniper oil has been used as a carminative and as an ingredient of herbal remedies for urinary-tract disorders and muscle and joint pain. It is also used in aromatherapy. Prolonged use may cause gastrointestinal irritation and there may be a risk of renal damage from high doses.

## Preparations

### Proprietary Preparations (details are given in Part 3)

**Ger.:** Caprisana†; Leukona-Stoffwechsel-Bad†; Roleca Wacholder.

**Multi-ingredient:** **Austral.:** Medinat PMT-Eze†; **Austria:** Berggeist; **Belg.:** Olbas; **Braz.:** Solvobil; **Ger.:** Dolo-cy; Kneipp Rheumabad; Nierentee 2000†; Nieroxin N†; Olbas; **Ital.:** Flodolor; Otosan Natural Ear Drops†; **Pol.:** Analgol; Olbas; Pinimol†; Pulmonil†; **S.Afr.:** Oleum Salviae Comp; **Spain:** Emolytar; Polytar; **Switz.:** Bain antirhumatismal†; Frixo-Dragon Vert†; Huile Po-Ho A. Vogel; LiberoL Baby N; Olbas; Pinimenthal Baby†; Spagyrom; Ziegella; **UK:** Diuretab; HealthAid Boldo-Plus; Olbas; Olbas for Children; Sciargo; St Johnswort Compound; Watershed.

## Kallidinogenase (BAN, rINN)

Callicrein; Kalidindinogenasa; Kalléone; Kallidinogenaasi; Kallidinogenas; Kallidinogénase; Kallidinogenasum; Kallikrein.

Каллидиногеназа

CAS — 9001-01-8.

ATC — C04AF01.

ATC Vet — QC04AF01.

**Pharmacopoeias.** In *Jpn.*

### Profile

Kallidinogenase is an enzyme isolated from the pancreas and urine of mammals. It converts kininogen to the kinin, kallidin. Kallidinogenase has been used in male infertility (p.2080) since the kallikrein-kinin system has a physiological role in the male genital tract. It also has vasodilating properties and has been used in the treatment of peripheral vascular disease (p.1178).

## Preparations

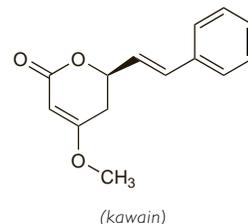
### Proprietary Preparations (details are given in Part 3)

**Austria:** Padutin.

## Kava

Kava-Kava.

CAS — 500-64-1 (*kawain*); 495-85-2 (*methysticin*); 500-62-9 (*yangonin*).



NOTE. The following terms have been used as 'street names' (see p.vi) or slang names for various forms of kava:

'ava; 'awa; Grog; Kawa; Lewena; Sakau; Waka; Wati; Yaqona.

### Profile

Kava is the rhizome of *Piper methysticum* (Piperaceae), a shrub indigenous to islands of the South Pacific. It contains pyrones including kawain, methysticin, and yangonin. Kava has been used in the South Pacific to produce an intoxicating beverage used for recreational purposes and during convalescence. It is reported to have sedative, skeletal muscle relaxant, and anaesthetic properties. It is given in some anxiety- and stress-related disorders. It was formerly used as an antiseptic and diuretic in inflammatory conditions of the genito-urinary tract in the form of a liquid extract. Kawain has also been used for nervous disorders and as a tonic.

A characteristic rash resembling that of pellagra occurs in some heavy consumers of kava. Extrapyramidal effects and cases of hepatitis have been reported. Preparations of kava for internal use have been withdrawn in the UK and some other western countries on account of its potential for serious hepatotoxic effects.

**Homoeopathy.** Kava has been used in homoeopathic medicines under the following names: Piper methysticum; Piper. m.

◇ References.

1. Anonymous. Kava. *Lancet* 1988; **ii**: 258–9.
2. Anonymous. Tonga trouble. *Pharm J* 1990; **245**: 288.
3. Ruze P. Kava-induced dermatopathy: a niacin deficiency? *Lancet* 1990; **335**: 1442–5.
4. Schelosky L, et al. Kava and dopamine antagonism. *J Neurol Neurosurg Psychiatry* 1995; **58**: 639–40.
5. Spillane PK, et al. Neurological manifestations of kava intoxication. *Med J Aust* 1997; **167**: 172–3.
6. Pepping J. Kava: piper methysticum. *Am J Health-Syst Pharm* 1999; **56**: 957–60.
7. Anonymous. Kava extract linked to hepatitis. *WHO Drug Inf* 2000; **14**: 98.
8. Escher M, et al. Hepatitis associated with kava, a herbal remedy for anxiety. *BMJ* 2001; **322**: 139.
9. Anonymous. Hepatic toxicity possibly associated with kava-containing products—United States, Germany, and Switzerland, 1999–2002. *MMWR* 2002; **51**: 1065–7. Also available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5147a1.htm> (accessed 15/07/04)
10. Stieckel F, et al. Hepatitis induced by Kava (Piper methysticum rhizoma). *J Hepatol* 2003; **39**: 62–7.
11. Clouatre DL. Kava kava: examining new reports of toxicity. *Toxicol Lett* 2004; **150**: 85–96.
12. Anke J, Ramzan I. Pharmacokinetic and pharmacodynamic drug interactions with Kava (Piper methysticum Forst. f.). *J Ethnopharmacol* 2004; **93**: 153–60.
13. Perez J, Holmes JF. Altered mental status and ataxia secondary to acute Kava ingestion. *J Emerg Med* 2005; **28**: 49–51.
14. Ulbricht C, et al. Safety review of kava (Piper methysticum) by the Natural Standard Research Collaboration. *Expert Opin Drug Saf* 2005; **4**: 779–94.

**Preparations**

**Proprietary Preparations** (details are given in Part 3)

**Braz.:** Ansiopax†; Calmiton†; Calmonex; Farnakava†; Kavakan; Kavalac†; Kavamed; Kavasedon†; Laitan; Natuzilium†; **Chile:** Laikan 100†; **Cz.:** Antares†; Kavasedon†; Leikan†; **Ger.:** Aigin†; Ardeydystin†; Eukavan†; Ka-Sabona†; Kava-Phyton†; Kavain Harras N†; Kavasedon†; Kavosporal forte†; Laitan†; Maon†; Nervonoclon N†; Neuronika†; **Mex.:** Laiken; **Switz.:** Kavasedon†; **Venez.:** Kavasedon†.

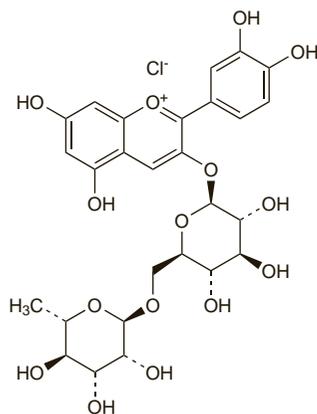
**Multi-ingredient:** **Ger.:** Bilicura Forte†; Hewepsychon duo†; Hyposedon N†; Kavosporal comp†; Somnuvis S†; **Ital.:** Controller; **Switz.:** Kawaforn†; Yakona N†.

**Keracyanin** (rINN)

Cyaninoid; Keracianina; Kéracyanine; Keracyaninum. 3-[6-O-(6-Deoxy- $\alpha$ -L-mannopyranosyl)- $\beta$ -D-glucopyranosyloxy]-3',4',5,7-tetrahydroxyflavylium chloride.

Керацианин

$C_{27}H_{31}ClO_{15}$  = 631.0.  
CAS — 18719-76-1.



**Profile**

Keracyanin is claimed to improve visual function in poor light conditions and has been given orally in vision disorders.

**Preparations**

**Proprietary Preparations** (details are given in Part 3)

**Ital.:** Meralopt†; **Spain:** Meralopt†.

**Keratinase**

Queratinasa.

CAS — 9025-41-6.

**Profile**

Keratinase is a proteolytic enzyme that has been obtained from cultures of *Streptomyces fradiae*. It can digest keratin, which is resistant to most proteolytic enzymes, in the presence of trace amounts of metal ions. It is used in the commercial separation of hair from animal hides, and has been tried as a depilatory; it has also been included in some topical antibacterial ointments, presumably to aid penetration of the active substances.

**Kinkeliba**

Combreti Folium; Kinkéliba.

**Pharmacopeias.** In *Fr.*

**Profile**

Kinkeliba is the dried leaves of *Combretum micranthum* (*C. alatum*; *C. raimbaultii*) (Combretaceae), a shrub indigenous to West Africa. It has been used as an ingredient of herbal remedies given for the treatment of biliary, liver, and gastrointestinal disorders. Other species of *Combretum* are also used.

**Homoeopathy.** Kinkeliba has been used in homoeopathic medicines.

**Preparations**

**Proprietary Preparations** (details are given in Part 3)

**Multi-ingredient:** **Fr.:** Hepaclem; Hepax; Jecopeptol; Mediflor Tisane Hepatique No 5; Romarene; Solution Stago Diluee. **Mon.:** Romarinex; **Switz.:** Bilifuge.

**Klebsiella Pneumoniae Glycoprotein**

Glucoproteina de Klebsiella pneumoniae; RU-41740.

**Profile**

*Klebsiella pneumoniae* glycoprotein is an immunostimulant that has been used in the management of respiratory-tract infections, wounds, and burns.

**Preparations**

**Proprietary Preparations** (details are given in Part 3)

**Braz.:** Biostim; **Cz.:** Biostim; **Fr.:** Biostim†; **Ital.:** Acintor; Biostim; **Mex.:** Biostim; **Port.:** Biostim†.

**Knotgrass**

Knoutweed; Nat' rdesna ptačicho; Pihatatar; Polygoni avicularis herba; Renouée des oiseaux; Takažoliq žolje; Trampgräs; Vogelknöterichkraut; Ziele rdestu ptasiego.

**Pharmacopeias.** In *Chin.* and *Eur.* (see p.vii).

**Ph. Eur. 6.2** (Knotgrass; Polygoni Avicularis Herba). It consists of the whole or cut, dried aerial parts of *Polygonum aviculare*. It contains not less than 0.3% of flavonoids, expressed as hyperoside ( $C_{21}H_{20}O_{12}$  = 464.4) calculated with reference to the dried drug. Protect from light.

**Profile**

Knotgrass, *Polygonum aviculare* (*P. heterophyllum*) (Polygonaceae), is included in herbal preparations for mild catarrh and associated upper respiratory-tract disorders.

**Homoeopathy.** Knotgrass has been used in homoeopathic medicines under the following names: Polygonum aviculare.

**Preparations**

**Proprietary Preparations** (details are given in Part 3)

**Multi-ingredient:** **Cz.:** Pulmoran; Species Urologicae Planta; **Pol.:** Cholesot; Reumosol.

**Krebiozen**

Crebiocién.

Кребиозен

CAS — 9008-19-9.

**Profile**

Krebiozen is the name of a preparation that was formerly promoted as a 'cancer cure' in the USA, but totally discredited by the FDA. It was stated to be obtained from the blood of horses previously injected with an extract of *Actinomyces bovis*.

**Kveim Antigen**

Antígeno de Kveim.

**Profile**

Kveim antigen is a fine suspension in physiological saline of sarcoid tissue prepared from spleens taken from patients with active sarcoidosis. It is used as an intradermal injection in the Kveim (Kveim-Siltzbach) test for the diagnosis of sarcoidosis (p.1512).

◇ References.

1. James DG, Williams WJ. Kveim-Siltzbach test revisited. *Sarcoidosis* 1991; **8**: 6–9.

◇ The safety of the Kveim test has been questioned, particularly with reference to the risk of transmission of sarcoidosis, and of hepatitis B, HIV, and Creutzfeldt-Jakob disease.<sup>1</sup> However, the procedure to identify acceptable sarcoid spleens and the method of preparation were considered sufficient to reduce the risk of transmission of infections<sup>2</sup> and of Creutzfeldt-Jakob disease.<sup>3</sup>

1. Wigly RD. Moratorium on Kveim tests. *Lancet* 1993; **341**: 1284.
2. du Bois RM, et al. Moratorium on Kveim tests. *Lancet* 1993; **342**: 173.
3. de Silva RN, Will RG. Moratorium on Kveim tests. *Lancet* 1993; **342**: 173.

**Laburnum**

Golden Chain; Golden Rain; Lluvia de oro.

**Profile**

All parts of laburnum, *Laburnum anagyroides* (*L. vulgare*; *Cytisus laburnum*) (Leguminosae), are toxic. The toxic principle is cytisine (p.2291) which has actions similar to nicotine.

**Lactic Acid**

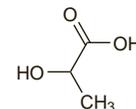
Acide lactique; Acidum lacticum; E270; E326 (potassium lactate); Kwas mlekowy; Kyselina mléčná; Láctico, ácido; Laktik Asit; Maitohappo; Milchsäure; Mjölksyra; Pieno rūgštis; Tejsav. 2-Hydroxypropionic acid; 2-Hydroxypropanoic acid.

$C_3H_6O_3$  = 90.08.

CAS — 50-21-5; 79-33-4 ((+)-lactic acid); 10326-41-7 ((-)-lactic acid); 598-82-3 ((±)-lactic acid).

ATC — G01AD01.

ATC Vet — QG01AD01; QP53AG02.



**Pharmacopeias.** In *Chin.*, *Int.*, *Jpn.* and *US.*

*Eur.* (see p.vii) includes monographs for the racemate and the (S)-enantiomer.

**Ph. Eur. 6.2** (Lactic Acid). A mixture of lactic acid, its condensation products, such as lactoyl-lactic acid and other poly-lactic acids, and water. The equilibrium between lactic acid and poly-lactic acids depends on the concentration and temperature. It is usually the racemate (*RS*-lactic acid), and contains the equivalent of 88 to 92% w/w of  $C_3H_6O_3$ . A colourless or slightly yellow, syrupy liquid. Miscible with water and with alcohol.

**Ph. Eur. 6.2** ((S)-Lactic Acid). A mixture of (S)-lactic acid, its condensation products, such as lactoyl-lactic acid and other poly-lactic acids, and water. The equilibrium between lactic acid and poly-lactic acids depends on the concentration and temperature. It contains the equivalent of 88 to 92% w/w of  $C_3H_6O_3$ , of which not less than 95% is the (S)-enantiomer. A colourless or slightly yellow, syrupy liquid. Miscible with water and with alcohol.

**USP 31** (Lactic Acid). A mixture of lactic acid and lactic acid lactate equivalent to a total of 88 to 92% w/w of  $C_3H_6O_3$ . It is obtained by the lactic fermentation of sugars or is prepared synthetically. Lactic acid obtained by fermentation of sugars is laevorotatory, while that prepared synthetically is racemic.

A colourless or yellowish, hygroscopic, practically odourless, syrupy liquid. When it is concentrated by boiling, lactic acid lactate is formed. Miscible with water, with alcohol, and with ether; insoluble in chloroform. Store in airtight containers.

**Adverse Effects and Treatment**

As for Hydrochloric Acid, p.2322, although in the concentrations used it is less corrosive.

**Neonates.** There was evidence that neonates had difficulty in metabolising *R*(-)-lactic acid and this isomer and the racemate should not be used in foods for infants less than 3 months old.<sup>1</sup>

1. FAO/WHO. Toxicological evaluation of certain food additives with a review of general principles and of specifications: seventeenth report of the joint FAO/WHO expert committee on food additives. *WHO Tech Rep Ser* 539 1974.

**Uses and Administration**

Lactic acid has actions similar to those of acetic acid (p.2244) and has been used similarly in the treatment of infective skin and vaginal disorders. It has been used in the preparation of lactate injections and infusions to provide a source of bicarbonate for the treatment of metabolic acidosis (for the problems of using lactate in metabolic acidosis, see p.1667). It is also applied topically in the treatment of warts (p.1584), often with salicylic acid, and in emollient creams. Other uses include the treatment of severe aphthous stomatitis in terminally ill, immunocompromised patients.

Lactic acid has also been used as a food preservative and as an ingredient of cosmetics.

**Preparations**

**BP 2008:** Lactic Acid Pessaries;

**USP 31:** Compound Cloquinol Topical Powder.

**Proprietary Preparations** (details are given in Part 3)

**Arg.:** Celucrem†; **Austria:** Espiritin; Warzin; **Belg.:** Lacta-Gynecogel; **Braz.:** Verrux; **Canada:** Dermalac; Lubriderm AHA†; Penederm†; **Chile:** Eucerin; **Fr.:** Ictyoderm†; Lactacyd Femina; **Ger.:** Lactisan; Lactisol; RMS†; **Irl.:** Relact; **Ital.:** Saugella; Intilac; Ungyn; **Malaysia:** Avecyde†; **Mex.:** Acid-Lac; Avecyde; Eucerin Piel con Tendencia Acneica†; Lactibon; **NZ:** BK†; **Philipp.:** Lactacyd VG; **Pol.:** Keratolysin; **Port.:** Atopic†; **Singapore:** Avecyde†; **Spain:** Keratidin; **Swed.:** Calmuri; **Switz.:** Vagoclyss; **USA:** Lactinol; Lactrex; **Venez.:** Dermalact; Jabolac†; Lactibon.

**Multi-ingredient:** **Arg.:** Acilac; Akerat; Callicida; Caminol†; Cellskinlab C + AHA; Coltix†; Controlacne; Democriodin; Duofilm; Hidrolac; Keracnyl; Lacticare; Muvar; Nutrafilm; Opoentrol†; Oxidermos; Pasem; Ureadin Facial; Verruclean; Verrutopic; **Austral.:** Aussie Tan Skin Moisturiser; Calmuri; Comkilt†; Dermadrate; Dermatech Wart Treatment; Duofilm; **Austria:** Calmuri; Calmuri HC; Duofilm; Helo-acid; Hylak; Hylak Forte; Lavagin; **Belg.:** Aporil; Calmuri†; **Braz.:** Calope†; Calotrat†; Colpolase;