Preparations

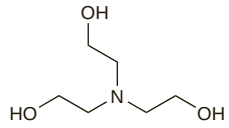
Proprietary Preparations (details are given in Part 3)
Multi-ingredient: ***Chile:*** Agua Sulfatada Picrica; ***Spain:*** Oftalmol Ocular.

Trolamine *(pINN)*

Trietanoloamina; Triethanolamine; Trolamiini; Trolamin; Trolamina; Trolaminas; Trolaminum.

Троламин

CAS — 102-71-6.



Description. Trolamine is a variable mixture of bases containing mainly 2,2′,2″-nitrilotriethanol (trolamine ($CH_2OH.CH_2)_3N$), together with 2,2′-iminobisethanol (diolamine) and smaller amounts of 2-aminoethanol (monoethanolamine).

Pharmacopoeias. In *Eur.* (see p.vii). Also in *USNF*.
Ph. Eur. 6.2 (Trolamine; Triethanolamine BP 2008). A clear, viscous, colourless or slightly yellow, very hygroscopic liquid. Miscible with water and with alcohol; soluble in dichloromethane. Store in airtight containers. Protect from light.
USNF 26 (Trolamine). A mixture of alkanolamines consisting largely of trolamine containing some diolamine and monoethanolamine. A colourless to pale yellow, viscous, hygroscopic liquid having a slight ammoniacal odour. Miscible with water and with alcohol; soluble in chloroform. Store in airtight containers. Protect from light.

Adverse Effects

Trolamine salts may be irritating to the skin and mucous membranes. Contact dermatitis has been reported after the use of ear drops containing trolamine polypeptide oleate-condensate.

Carcinogenicity. Because of concern about the possible production of carcinogenic nitrosamines in the stomach, the Swiss authorities restricted the use of trolamine to preparations for external use.[1]

1. Anonymous. Trolamine: concerns regarding potential carcinogenicity. *WHO Drug Inf* 1991; **5:** 9.

Uses and Administration

Trolamine is used with fatty acids such as stearic and oleic acids as an emulsifier and as an alkalinising agent. It has also been used to reduce dithranol-induced staining of the skin.

Ear drops containing trolamine polypeptide oleate-condensate 10% are used for the removal of impacted ear wax (p.1725).

Trolamine salicylate (p.132) has also been used.

Radiotherapy. An emulsion of trolamine has been widely used in the treatment and prevention of radiation-induced dermatitis in patients undergoing radiotherapy. However, several studies have suggested that it is of little or no benefit.[1-3]

1. Fisher J, *et al.* Randomized phase III study comparing best supportive care to Biafine as a prophylactic agent for radiation-induced skin toxicity for women undergoing breast irradiation: Radiation Therapy Oncology Group (RTOG) 97-13. *Int J Radiat Oncol Biol Phys* 2000; **48:** 1307–10.
2. Szumacher E, *et al.* Phase II study assessing the effectiveness of Biafine cream as a prophylactic agent for radiation-induced acute skin toxicity to the breast in women undergoing radiotherapy with concomitant CMF chemotherapy. *Int J Radiat Oncol Biol Phys* 2001; **51:** 81–6.
3. Elliott EA, *et al.* Phase III trial of an emulsion containing trolamine for the prevention of radiation dermatitis in patients with advanced squamous cell carcinoma of the head and neck: results of Radiation Therapy Oncology Group Trial 99-13. *J Clin Oncol* 2006; **24:** 2092–7.

Preparations

Proprietary Preparations (details are given in Part 3)
Arg.: Biafine; Orla-Wax†; Solucer; ***Austral.:*** Neutrogena; ***Belg.:*** Xerumenex; ***Canad.:*** Cerumenex; ***Chile:*** Biafine; ***Fr.:*** Biafine; Lamiderm; ***Ger.:*** Cerumenex N; ***Hong Kong:*** Biafine; ***Israel:*** Biafine; ***Malaysia:*** Biafine†; ***Mex.:*** Orlawax; ***S.Afr.:*** Cerumenex†; ***Singapore:*** Biafine†; ***Switz.:*** Biafine; Cerumenex; ***USA:*** Biafine; Cerumenex†; ***Venez.:*** Biafine.

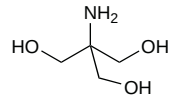
Multi-ingredient: ***Arg.:*** Eucos-L†; Onixol†; Tereosit†; ***Braz.:*** Cerumin; Paraqueimol; ***Canad.:*** Soropon; ***Ital.:*** Dopo Pik; ***USA:*** Maxilube.

Trometamol *(BAN, rINN)* ⊗

NSC-6365; THAM; Trihydroxymethylaminomethane; TRIS; Tris(hydroksymetylo)aminometan; Tris(hydroxymethyl)aminomethane; Trométamol; Trometamoli; Trometamolis; Trometamolum; Tromethamine *(USAN)*. 2-Amino-2-(hydroxymethyl)propane-1,3-diol.

Трометамол

$C_4H_{11}NO_3$ = 121.1.
CAS — 77-86-1.
ATC — B05BB03; B05XX02.
ATC Vet — QB05BB03; QB05XX02.



Pharmacopoeias. In *Eur.* (see p.vii) and *US*.
Ph. Eur. 6.2 (Trometamol). A white or almost white, crystalline powder or colourless crystals. Freely soluble in water; sparingly soluble in alcohol; very slightly soluble in ethyl acetate. A 5% solution in water has a pH of 10.0 to 11.5.
USP 31 (Tromethamine). A white, crystalline powder having a slight characteristic odour. Soluble 1 in 1.8 of water and 1 in 45.5 of alcohol; freely soluble in low-molecular-weight aliphatic alcohols; practically insoluble in carbon tetrachloride, in chloroform, and in benzene. pH of a 5% solution in water is between 10.0 and 11.5. Store in airtight containers.

Incompatibilities. There is evidence to suggest that fluorouracil degrades to cardiotoxic compounds in formulations buffered with trometamol.[1]

1. Lukaschek J, *et al.* Cardiotoxicity and neurotoxicity of high-dose continuous fluorouracil as a result of degradation compounds in the drug vials. *J Clin Oncol* 2004; **22:** 5022–5.

Adverse Effects and Precautions

Great care must be taken to avoid extravasation at the injection site as solutions may cause tissue damage. Local irritation, venospasm and phlebitis have occurred.

Respiratory depression can occur and mechanical ventilation may be required. Hypoglycaemia may also occur. Trometamol is contra-indicated in anuria and uraemia, and should be used cautiously in patients with renal impairment as hyperkalaemia has been reported in such patients. Trometamol is not recommended for use in patients with respiratory acidosis alone. If it is used in patients with respiratory acidosis accompanying metabolic acidosis, ventilation should be maintained mechanically. Trometamol is contra-indicated in chronic respiratory acidosis.

Blood concentrations of bicarbonate, glucose, and electrolytes, partial pressure of carbon dioxide, and blood pH should be monitored during infusion of trometamol.

Uses and Administration

Trometamol is an organic amine proton acceptor used as an alkalinising agent in the treatment of metabolic acidosis (p.1667). It also acts as a weak osmotic diuretic. Trometamol is mainly used during cardiac bypass surgery and during cardiac arrest. It may also be used to reduce the acidity of citrated blood for use in bypass surgery.

The dose used should be the minimum required to increase the pH of the blood to within normal limits and is based on the bodyweight and the base deficit. Trometamol is given by slow intravenous infusion as a 0.3M solution; it should not be given for longer than a day except in life-threatening emergencies.

Trometamol citrate is given by mouth for the management of urinary calculi and acidosis. Trometamol acefyllinate has also been used for acidosis.

◊ References.

1. Nahas GG, *et al.* Guidelines for the treatment of acidaemia with THAM. *Drugs* 1998; **55:** 191–224.

Preparations

USP 31: Tromethamine for Injection.

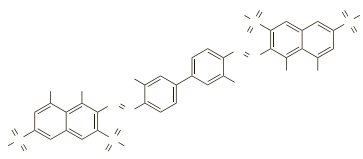
Proprietary Preparations (details are given in Part 3)
Austral.: Tham; ***Austria:*** Tris; ***Ger.:*** Tham; Tris; ***Ital.:*** Thamesol; ***Swed.:*** Addex-THAM.

Multi-ingredient: ***Arg.:*** Solocalm Plus; ***Austral.:*** Blink-N-Clean; ***Fr.:*** Alcaphor; ***Norw.:*** Tribonat; ***Swed.:*** Theranyl†; Tribonat; ***Switz.:*** Saltrates†.

Trypan Blue

CI Direct Blue 14; Colour Index No. 23850; Trypanum Caeruleum. Tetrasodium 3,3′-[(3,3′-dimethylbiphenyl-4,4′-diyl)bisazo]-bis[5-amino-4-hydroxynaphthalene-2,7-disulphonate].

$C_{34}H_{24}N_6Na_4O_{14}S_4$ = 960.8.
CAS — 72-57-1.



Profile

Trypan blue solutions are used as stains in microscopy and for visualisation of various tissues as an aid to ophthalmic surgery.

◊ References.

1. Werner L, *et al.* Permanent blue discoloration of a hydrogel intraocular lens by intraoperative trypan blue. *J Cataract Refract Surg* 2002; **28:** 1279–86.
2. Haritoglou C, *et al.* Functional outcome after trypan blue-assisted vitrectomy for macular pucker: a prospective, randomized, comparative trial. *Am J Ophthalmol* 2004; **138:** 1–5.
3. Gouws P, *et al.* Cystoid macular oedema with trypan blue use. *Br J Ophthalmol* 2004; **88:** 1348–9.
4. Lee KL, *et al.* A comparison of outcomes after indocyanine green and trypan blue assisted internal limiting membrane peeling during macular hole surgery. *Br J Ophthalmol* 2005; **89:** 420–4.
5. Healey PR, Crowston JG. Trypan blue identifies antimetabolite treatment area in trabeculectomy. *Br J Ophthalmol* 2005; **89:** 1152–6.
6. Roos JC, Kerr Muir MG. Use of trypan blue for penetrating keratoplasty. *J Cataract Refract Surg* 2005; **31:** 1867–9.

Preparations

Proprietary Preparations (details are given in Part 3)
Ital.: Oftalblu; ***Neth.:*** MembraneBlue; VisionBlue; ***USA:*** VisionBlue.
Multi-ingredient: ***Fr.:*** Parkipan†.

Trypsin *(BAN)*

Thrypsinum; Tripsina; Tripsinas; Tripszin; Trypsiini; Trypsine; Trypsinum; Trypsyna.

CAS — 9002-07-7.
ATC — B06AA07; D03BA01.
ATC Vet — QB06AA07; QD03BA01.

Pharmacopoeias. In *Chin.*, *Eur.* (see p.vii), and *US*.
Ph. Eur. 6.2 (Trypsin). A proteolytic enzyme obtained by the activation of trypsinogen extracted from mammalian pancreas. It has an activity of not less than 0.5 microkatals/mg, calculated with reference to the dried substance. A white or almost white, crystalline or amorphous powder; the amorphous form is hygroscopic. Sparingly soluble in water. A 1% solution in water has a pH of 3.0 to 6.0. Solutions have a maximum stability at pH 3 and a maximum activity at pH 8. Store at 2° to 8° in airtight containers. Protect from light.
USP 31 (Crystallized Trypsin). A proteolytic enzyme crystallised from an extract of the pancreas of healthy bovine or porcine animals, or both. It contains not less than 2500 USP units in each mg, calculated on the dried basis. A white to yellowish-white, odourless, crystalline or amorphous powder. Store in airtight containers at temperature not exceeding 40°.

Profile

Trypsin is a proteolytic enzyme that has been applied for the debridement of wounds. It has also been taken by mouth, usually with chymotrypsin (p.2281), and sometimes with antibacterial or other drugs, for its supposed benefit in relieving oedema and inflammation associated with infection or trauma. Trypsin solutions have been inhaled for the liquefaction of viscous sputum, and trypsin is also an ingredient of mixtures intended to relieve various gastrointestinal disorders. Trypsin has been used in oncology in a combination preparation with chymotrypsin and papain (see under Uses and Administration of Papain, p.2362).

Hypersensitivity reactions may occasionally occur.

Preparations

Proprietary Preparations (details are given in Part 3)
Multi-ingredient: ***Arg.:*** Phlogenzym†; ***Austria:*** Leukase; Leukase-Kegel; Phlogenzym; Rutozym; Traumazym; Wobenzym; ***Braz.:*** Parenzyme; Parenzyme Ampicilina; Parenzyme Analgesico; Parenzyme Tetraciclina; ***Cz.:*** Phlogenzym; Wobe-Mugos†; Wobenzym; ***Fr.:*** Ribatran; ***Ger.:*** Enzym-Wied†; Mulsal N†; Phlogenzym; Wobe-Mugos E†; Wobenzym N†; ***Gr.:*** Chymoral; ***Hung.:*** Phlogenzym; Trypsin†; ***India:*** Alfapsin; Orthal Forte; Soluzyme; ***Ital.:*** Essen Enzimatico†; ***Jpn:*** Kimotab; ***Mex.:*** Ochozim; Phlogenzym; Quimotrip; Ribotripsin; Wobe-Mugos; Wobenzym; Zimotris; ***Port.:*** Anginova; Chimar; ***Rus.:*** Phlogenzym (Флогэнзим); Wobe-Mugos E (Вобэ-Муос Е); Wobenzym (Вобэнзим); ***Spain:*** Bristaciclina Dental; Dertrase; Dosil Enzimatico; Doxiten Enzimatico; Kanapomada; Naso Pekamin; Oxidermiol Enzima†; Quimodril; ***USA:*** Allanderm-T; Dermuspray; Granulderm; Granulex; GranuMed; Xenaderm; ***Venez.:*** Phlogenzym; Wobenzym N.

Tuberculins

Tuberculinas.

ATC — V04CF01.
ATC Vet — QV04CF01.

NOTE. 'PPD' is an abbreviation sometimes used for tuberculin purified protein derivative which should not be confused with paraphenylenediamine (p.2363), which is also referred to by the same abbreviation.

Pharmacopoeias. In *Eur.* (see p.vii) and *US*.
Ph. Eur. 6.2 (Tuberculin for Human Use, Old). It consists of a filtrate, concentrated by heating, containing the soluble products of the culture and lysis of one or more strains of *Mycobacterium tuberculosis* and/or *M. bovis*. It contains a suitable preservative that does not give rise to false-positive reactions. In concentrated form, it is a transparent, viscous, yellow or brown liquid. Protect from light.
Ph. Eur. 6.2 (Tuberculin Purified Protein Derivative for Human Use). A preparation obtained by precipitation from the heated

products of the culture and lysis of *Mycobacterium tuberculosis* and/or *M. bovis*. It contains a suitable preservative that does not give rise to false-positive reactions. It is a colourless or pale yellow liquid; the diluted preparation may be a freeze-dried powder which upon dissolution gives a colourless or pale yellow liquid. Protect from light.

USP 31 (Tuberculin). A sterile solution derived from the concentrated, soluble products of growth of the tubercle bacillus (*Mycobacterium tuberculosis* or *M. bovis*) prepared in a special medium. It is provided either as Old Tuberculin, a culture filtrate adjusted to the standard potency by the addition of glycerol and isotonic sodium chloride solution, or as Purified Protein Derivative (PPD), a further purified protein fraction. Store at 2° to 8°.

Adverse Effects

Pain and pruritus may occur at the injection site, occasionally with vesiculation, ulceration, or necrosis in highly sensitive persons. Granuloma has been reported.

Nausea, headache, dizziness, malaise, rash, urticaria, oedema, and pyrexia have been reported occasionally; immediate systemic hypersensitivity, including anaphylaxis, has been reported rarely. There have also been rare reports of lymphangitis.

Hypersensitivity. There are rare reports[1-4] of severe anaphylactic or anaphylactoid reactions, occasionally fatal,[1] to tuberculin.

1. DiMaio VJM, Froede RC. Allergic reactions to the tine test. *JAMA* 1975; **233:** 769.
2. Spiteri MA, *et al.* Life threatening reaction to tuberculin testing. *BMJ* 1986; **293:** 243–4.
3. Wright DN, *et al.* Systemic and local allergic reactions to the tine test purified protein derivative. *JAMA* 1989; **262:** 2999–3000.
4. Sanofi Pasteur, Canada. Risk of serious allergic reactions following TUBERSOL [Tuberculin Purified Protein Derivative (Mantoux)] administration (issued 19th May 2005). Available at: http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/medeff/tubersol_hpc-cps-eng.pdf (accessed 08/08/08)

Lymphangitis. Lymphangitis has been reported on 5 occasions after the Mantoux test and on 7 occasions after the Heaf test.[1] However, it was noted that a tuberculin test may have been inappropriate in some of these patients, particularly older subjects and those with evidence of healed tuberculous lesions.[2]

1. Morrison JB. Lymphangitis after tuberculin tests. *BMJ* 1984; **289:** 413.
2. Festenstein F. Lymphangitis after tuberculin tests. *BMJ* 1984; **289:** 625–6.

Precautions

Tuberculin should be given with caution to patients who have, or are suspected of having, active tuberculosis; although severe local reactions may occur in patients with active tuberculosis, sensitivity may be diminished if it is particularly severe. Sensitivity to tuberculin may also be diminished in the following conditions: viral or severe bacterial infection including HIV infection and infectious mononucleosis; neoplastic disease particularly lymphoma; sarcoidosis; corticosteroid or immunosuppressive therapy; recent use of live virus vaccines; ultraviolet light treatment; chronic renal failure; dehydration; and malnutrition.

Tuberculins may be adsorbed onto the surface of syringes and should therefore be given immediately.

Uses and Administration

Tuberculin skin tests are used to detect tuberculoprotein hypersensitivity when BCG vaccination is being considered or as an aid to diagnosis of tuberculosis. A person showing a specific sensitivity to tuberculin is considered to have been infected with the tubercle bacillus, though the infection may be inactive. Tuberculin for sensitivity testing is given by intradermal injection as in the Mantoux test. Multiple-puncture devices such as the Heaf test or tine tests have also been used, although they are no longer available in the UK.

In the UK, it is recommended that tuberculin testing should always be performed when BCG vaccination is being considered, and the **Mantoux** test is recommended. For a routine Mantoux test, a diluted solution of tuberculin purified protein derivative (PPD) is given by intradermal injection and the reaction, which is graded by the degree of induration, read 48 to 72 hours later. A retest with a stronger solution of PPD may be considered if the results of the initial test are unclear. Different commercial preparations vary in labelling format and potency, and doses and interpretation of results cannot therefore be extrapolated from one preparation to another.

Individuals with no or minimal reactions who have not previously been given BCG vaccines may be offered BCG vaccination. Patients with a positive reaction are considered to be hypersensitive to tuberculoprotein and should not be vaccinated. Investigation for the presence of active tuberculosis is generally only indicated for patients showing a strongly positive reaction to a tuberculin skin test. However, there are many factors that should be considered when interpreting the results; in addition to those listed under Precautions (see above), there are the effects of previous BCG vaccination, repeated tuberculin testing, and age. In some areas, a positive reaction may be a result of cross-sensitivity of the test to non-tuberculous mycobacteria (see below).

For the **Heaf** test, a solution of PPD is applied to the forearm using a multiple-puncture gun (Heaf gun), and the reaction evaluated about a week later.

The term **tine** test is generally used for disposable multiple-puncture devices coated with dried old tuberculin or PPD. However, some consider tine tests to be unreliable.

In some other countries, the population tested, the procedures used, and grading of reactions may differ slightly from that outlined above.

Tuberculins have also been used, in conjunction with other antigens, for anergy testing to assess the status of cell-mediated immunity.

Latent tuberculosis. Full eradication of tuberculosis from developed countries requires identification of latent as well as active cases.[1] Tuberculin testing has been in use for over 100 years and, while still considered a useful diagnostic agent for tuberculosis, the problems of false-positive reactions or reduced sensitivity to the test are well recognised.[1] Use of the test to identify latent disease has evolved with experience.[2] Previous BCG vaccination is one factor that significantly increases the likelihood of a false-positive reaction to tuberculin testing, which makes the diagnosis of latent tuberculosis particularly difficult.[3] Interpretation of the skin test should therefore be made by considering the induration size in the context of the individual clinical profile, including other risk factors for infection.[2,3] Three different approaches to assess the annual risk of tuberculous infection using tuberculin testing gave different results in a study of schoolchildren who had been given BCG vaccinations early in life.[4] This led the authors to conclude that the effect of previous BCG vaccination on tuberculin reactivity may be more complex than assumed, and that the tuberculin test is a poor indicator of latent infection. It has been suggested[2] that it is not necessary for low-risk persons in the general population of the USA to receive routine tuberculin testing for tuberculosis; high-risk groups of adults and children for whom screening might be warranted have been defined, and consensus recommendations made. An opinion has also been ventured[5] that tuberculin testing before BCG vaccination is not necessary in children in the UK.

1. Lee E, Holzman RS. Evolution and current use of the tuberculin test. *Clin Infect Dis* 2002; **34:** 365–70.
2. American Thoracic Society. Targeted tuberculin testing and treatment of latent tuberculosis infection. 1999. Available at: http://www.thoracic.org/sections/publications/statements/pages/mtpi/latenttb1-27.html (accessed 14/07/06)
3. Wang L, *et al.* A meta-analysis of the effect of Bacille Calmette Guérin vaccination on tuberculin skin test measurements. *Thorax* 2002; **57:** 804–9. Correction: *ibid.* 2003; **58:** 188.
4. Leung CC, *et al.* Tuberculin response in BCG vaccinated schoolchildren and the estimation of annual risk of infection in Hong Kong. *Thorax* 2005; **60:** 124–9.
5. Bothamley GH, *et al.* Tuberculin testing before BCG vaccination. *BMJ* 2003; **327:** 243–4.

Malignant disease. Benefit has been reported[1] in 2 patients with adult T-cell leukaemia/lymphoma predominantly involving the skin after local treatment with tuberculin purified protein derivative.

1. Kanekura T, *et al.* Purified protein derivative treatment for skin lesions of adult T-cell leukaemia/lymphoma. *Br J Dermatol* 1999; **140:** 767–8.

Non-tuberculous mycobacterial infection. The tuberculin skin test is not specific for *Mycobacterium tuberculosis*, but can also represent a cross-reaction caused by antigens on other non-tuberculous mycobacteria. Re-examination[1] of results from children with non-tuberculous mycobacterial infection concluded that the avian Mantoux test (avian tuberculin purified protein derivative (PPD) prepared from *M. avium*) was more sensitive than the human Mantoux test (tuberculin PPD prepared from *M. tuberculosis*) in the detection of non-tuberculous mycobacteria in regions with a low incidence of tuberculosis, and may be a useful aid to differential diagnosis in areas where tuberculosis is prevalent.

1. Daley AJ, Isaacs D. Differential avian and human tuberculin skin testing in non-tuberculous mycobacterial infection. *Arch Dis Child* 1999; **80:** 377–9.

Preparations

Ph. Eur.: Old Tuberculin for Human Use; Tuberculin Purified Protein Derivative for Human Use;
USP 31: Tuberculin.

Proprietary Preparations (details are given in Part 3)
Austria: Monotest; ***Belg.:*** Monovacc-Test†; ***Canad.:*** Tubersol; ***Fr.:*** Monotest†; Tubertest; ***Ger.:*** Tubergen-Test†; ***Gr.:*** Imotest Tuberculin; ***Ital.:*** Biocine Test PPD; Monotest†; ***NZ:*** Monotest†; Tubersol; ***S.Afr.:*** Biocine Test; Japan Freeze-Dried Tuberculin; Monotest†; ***Spain:*** Tubersol PPD†; ***Swed.:*** Monotest†; ***USA:*** Aplisol; Tubersol; ***Venez.:*** Imotest Tuberculina†.

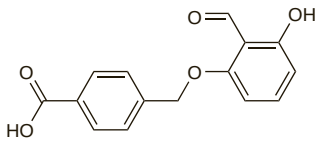
Multi-ingredient: ***Austral.:*** Multitest CMI; ***Austria:*** Multitest; ***Cz.:*** Imunoskintest†; ***Ger.:*** Multitest†; ***Israel:*** Multitest CMI; ***NZ:*** Multitest CMI†; ***S.Afr.:*** Multitest CMI†.

Tucaresol *(BAN, rINN)* ⊗

BW-589C; 589C; 589C80; Tucarésol; Tucaresolum. α-(2-Formyl-3-hydroxyphenoxy)-*p*-toluic acid.

Тукарезол

$C_{15}H_{12}O_5$ = 272.3.
CAS — 84290-27-7.



Profile

Tucaresol is reported to interact with haemoglobin to increase oxygen affinity. It has been investigated as an oral drug for the treatment of sickle-cell disease (p.1044). Tucaresol is also reported to have immunostimulant properties and is under investigation in HIV infection and hepatitis B. Hypersensitivity reactions have occurred.

◊ References.

1. Rolan PE, *et al.* The pharmacokinetics, tolerability and pharmacodynamics of tucaresol (589C80; 4[2-formyl-3-hydroxyphenoxymethyl]benzoic acid), a potential anti-sickling agent, following oral administration to healthy subjects. *Br J Clin Pharmacol* 1993; **35:** 419–25.
2. Arya R, *et al.* Tucaresol increases oxygen affinity and reduces haemolysis in subjects with sickle cell anaemia. *Br J Haematol* 1996; **93:** 817–21.
3. Peck RW, *et al.* Effect of food and gender on the pharmacokinetics of tucaresol in healthy volunteers. *Br J Clin Pharmacol* 1998; **46:** 83–6.
4. Gori A, *et al.* Immunomodulation induced by tucaresol in HIV infection: results of a 16 week pilot Phase I/II trial. *Antivir Ther* 2004; **9:** 603–14.

Javanese Turmeric

Curcuma Zanthorrhiza; Curcumae Javanicae; Curcumae xanthorrhizae rhizoma; Geltonšaknių ciberžolių šakniastiebiai; Gurkmeja, javanesisk; Jaavan kurkuma; Jávai-kurkuma gyökértörzs; Oddenek kurkumy žlutokořenné; Temoe lawacq; Temoe Lawak; Témoé-lawaq.

Pharmacopoeias. In *Eur.* (see p.vii).
Ph. Eur. 6.2 (Turmeric, Javanese). It consists of the dried rhizome, cut in slices, of *Curcuma xanthorrhiza*. It contains not less than 5% v/w of essential oil and not less than 1% of dicinnamoyl methane derivatives expressed as curcumin, both calculated with reference to the anhydrous drug. It has an aromatic odour. Protect from light.

Profile

Javanese turmeric is an ingredient of preparations indicated for biliary and gastrointestinal disorders. It is a close relative of the spice turmeric (p.1473), which has been used similarly.

Irritable bowel syndrome. For reference to the ineffectiveness of Javanese turmeric in patients with irritable bowel syndrome see under Fumitory, p.2307.

Preparations

Proprietary Preparations (details are given in Part 3)
Cz.: Gallentee†; ***Ger.:*** Bilagit Mono†; Curcu-Truw; Curcumen; Infi-tract; Pankreaplex mono.

Multi-ingredient: ***Austria:*** Choleodoron; ***Fr.:*** Hepaclem; ***Ger.:*** Bilisan Duo; Cholosom SL†; Cholosom-Tee; Divalol W†; Enzym-Harongan; Gallexier; Hepaticum novo†; Infi-tract†; ***Hong Kong:*** Hepatofalk; ***Indon.:*** Curliv; Curliv Plus; Curson; Gramuno; Hepa-Q; Hepacell; Hepatofalk Planta; Hepimun; Librozym; Norflam; Verona; ***S.Afr.:*** Choleodoron; ***Singapore:*** Hepatofalk Planta; ***Switz.:*** Choleodoron†.

Turpentine Oil

Aetheroleum Terebinthinae; Esencia de Trementina; Essence de Térébenthine; Oleum Terebinthinae; Oleum Terebinthinae Depuratum; Rectified Turpentine Oil; Spirits of Turpentine; Térébenthine, huile essentielle de; Terebentin Yağı; Terebinthini aetheroleum; Terebintin Esansı; Trementina, aceite esencial de.

Pharmacopoeias. In *Chin.*, *Eur.* (see p.vii), and *Jpn*.
Ph. Eur. 6.2 (Turpentine Oil, Pinus Pinaster Type; Terebinthini Aetheroleum ab Pinum Pinastrum). An essential oil obtained by steam distillation, followed by rectification at a temperature below 180°, from the oleoresin obtained by tapping *Pinus pinaster*. A suitable antioxidant may be added. It contains 70.0 to 85.0% α-pinene, 0.5 to 1.5% camphene, 11.0 to 20.0% β-pinene, maximum 1% car-3-ene, 0.4 to 1.5% β-myrcene, 1.0 to 7.0% limonene, 0.2 to 2.5% longifolene, 0.1 to 3.0% β-caryophyllene, and maximum 1.0% caryophyllene oxide.
A clear, colourless or pale yellow liquid with a characteristic odour. Relative density 0.856 to 0.872. Store in well-filled airtight containers at a temperature not exceeding 25°. Protect from light.

Adverse Effects

In poisoning with turpentine oil there may be local burning and gastrointestinal upset, coughing and choking, pulmonary oedema, excitement, coma, fever, tachycardia, liver damage, haematuria, and albuminuria. Fatalities have occurred.