

## Preparations

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

**Multi-ingredient:** *Austria:* Menodoron; *Fr.:* Dystolise; *Neth.:* Luuf Verkoudheidsbalsem (voor babies); *Pol.:* Salviasept; *S.Afr.:* Menodoron; *Spain:* Natusor Sinulanj.

## Mastic

Almáciga; Mastiche; Mastiksi; Mastix; Pistacijų mastika.

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

**Ph. Eur. 6.2** (Mastic). The dried resinous exudate obtained from stems and branches of *Pistacia lentiscus* var. *latifolius*. It contains a minimum of 1% v/w of essential oil, calculated with reference to the anhydrous drug. It should not be powdered.

## Profile

Solutions of mastic in alcohol, chloroform, or ether have been used, applied on cotton wool, as temporary fillings for carious teeth. Compound Mastic Paint (BP 1980) was formerly used as a protective covering for wounds and to hold gauze in position. Mastic gum has been used in the management of peptic ulcer disease.

**Peptic ulcer disease.** Mastic may be effective in the treatment of peptic ulcer disease possibly due to an antibacterial action on *Helicobacter pylori*.<sup>1</sup> However, one small clinical study found no benefit.<sup>2</sup>

1. Huwez FU, *et al.* Mastic gum kills *Helicobacter pylori*. *N Engl J Med* 1998; **339**: 1946. Correction. *ibid.*: **340**: 576 [dose].
2. Bebb JR, *et al.* Mastic gum has no effect on *Helicobacter pylori* load in vivo. *J Antimicrob Chemother* 2003; **52**: 522–3.

## Preparations

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**UK:** Mastika.

## Meadowsweet

Älgörst; Filipendulae ulmariae herba; Mesiangervo; Nat' tužebniku jilmovéhó; Pelkinių vingiorykščių žolė; Queen of the Meadows; Reina de los prados; Reine des Prés; Reine des prés, sommité fleurie de; Spiraeae Herba; Ulmaria.

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

**Ph. Eur. 6.2** (Meadowsweet). The whole or cut, dried flowering tops of *Filipendula ulmaria* (*Spiraea ulmaria*). It contains a minimum of 0.1% v/w of steam-volatile substances (dried drug). It has an aromatic odour of methyl salicylate after crushing.

## Profile

Meadowsweet is used in herbal medicine as a diuretic and in gastrointestinal and rheumatic disorders.

**Homoeopathy.** Meadowsweet has been used in homoeopathic medicines under the following names: *Filipendula ulmaria*; *Spiraea ulmaria*; *Spiraea ulmaria ex herba*; *Filip. ul.*

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**Multi-ingredient:** **Cz.:** Antirevmaticky Caj; **Fr.:** Drainuryl; Mediflor: Tisane Antrhumatisme No 2; Mediflor Tisane No 4 Diuretique; Polypirine; **Ital.:** Rodolor; Neuralta Migren; Plk Gel; Sambuco (Specie Composta); Tiglio (Specie Composta); **Mex.:** Rodan; **Pol.:** Reumaherb; **Spain:** Dolosul; Natusor Harpagosinol; Natusor Renal; **Switz.:** Urinex; **UK:** Acidosis; Indigestion Mixture; **USA:** Amengel.

## Meclofenoxate Hydrochloride (BANM, rINN) ⓧ

Centrophoxine Hydrochloride; Clofenoxine Hydrochloride; Clophenoxate Hydrochloride; Deanol 4-Chlorophenoxyacetate Hydrochloride; Hidrocloruro de meclofenoxato; Meclofenoxane Hydrochloride; Méclofenoxate, Chlorhydrate de; Meclofenoxati Hydrochloridum. 2-Dimethylaminoethyl 4-chlorophenoxyacetate hydrochloride.

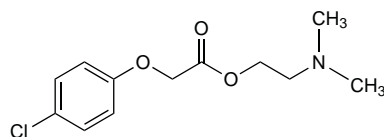
Меклофеноксат Гидрохлорид

$C_{12}H_{16}ClNO_3 \cdot HCl = 294.2$ .

CAS — 51-68-3 (meclofenoxate); 3685-84-5 (meclofenoxate hydrochloride).

ATC — N06BX01.

ATC Vet — QN06BX01.



(meclofenoxate)

**Pharmacopoeias.** In *Chin.* and *Jpn.*

## Profile

Meclofenoxate hydrochloride has been claimed to aid cellular metabolism in the presence of diminished oxygen concentrations. It has been given mainly for mental changes in the elderly, or after strokes or head injury.

## Preparations

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

*Austria:* Lucidril; *Ger.:* Cerutilf; Helfergin; *Hung.:* Helfergin.

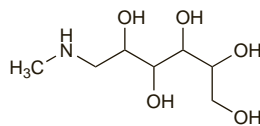
## Meglumine (BAN, rINN)

Meglumini; Meglumin; Meglumina; Megluminas; Méglumine; Megluminum. *N*-Methylglucamine; 1-Methylamino-1-deoxy-D-glucitol.

Меглюмин

$C_7H_{17}NO_5 = 195.2$ .

CAS — 6284-40-8.



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

**Ph. Eur. 6.2** (Meglumine). A white or almost white, crystalline powder. Freely soluble in water; sparingly soluble in alcohol; practically insoluble in dichloromethane.

**USP 31** (Meglumine). White to faintly yellowish-white, odourless crystals or powder. Freely soluble in water; sparingly soluble in alcohol.

## Profile

Meglumine is an organic base used for the preparation of salts of organic acids including many used as contrast media.

## Melaleuca Oil

Australian Tea Tree Oil; Melaleuca, aceite de; Mélealeuca, huile essentielle de; Melaleucaae aetheroleum; Melaleucaae Etheroleum; Mirteniy eterinis aliejus; Oleum Melaleucaae; Silice kajeputu střidavolistého; Tea Tree Oil; Teepuuöljy; Teträdölja.

CAS — 68647-73-4; 8022-72-8.

**NOTE.** Though the synonym Ti-tree Oil has been used for melaleuca oil (e.g. in BPC 1949), the name Ti-tree is also applied to species of *Condyline* (Liliaceae) indigenous to New Zealand.

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

**Ph. Eur. 6.2** (Tea Tree Oil). The essential oil obtained by steam distillation from the foliage and terminal branchlets of *Melaleuca alternifolia*, *M. linariifolia*, *M. dissitiflora*, and/or other species of *Melaleuca*. It contains less than 7.0% aromadendrene, less than 15% cineol, 0.5 to 12.0% *p*-cymene, 0.5 to 4.0% limonene, 1.0 to 6.0%  $\alpha$ -pinene, less than 3.5% sabinene, 5.0 to 13.0%  $\alpha$ -terpinene, 10.0 to 28.0%  $\gamma$ -terpinene, minimum of 30% terpinen-4-ol, 1.5 to 8.0%  $\alpha$ -terpineol, and 1.5 to 5.0% terpinolene. A clear, mobile, colourless to pale yellow liquid with a characteristic odour. Store in well-filled airtight containers at a temperature not exceeding 25°. Protect from light.

A clear, mobile, colourless to pale yellow liquid with a characteristic odour. Store in well-filled airtight containers at a temperature not exceeding 25°. Protect from light.

## Profile

Melaleuca oil has bactericidal and fungicidal properties and is used topically for various skin disorders. It is also used in aromatherapy.

## References.

1. Carson CF, *et al.* Efficacy and safety of tea tree oil as a topical antimicrobial agent. *J Hosp Infect* 1998; **40**: 175–8.
2. Allen P. Tea tree oil: the science behind the antimicrobial hype. *Lancet* 2001; **358**: 1245.
3. Satchell AC, *et al.* Treatment of interdigital tinea pedis with 25% and 50% tea tree oil solution: a randomized, placebo-controlled, blinded study. *Australas J Dermatol* 2002; **43**: 175–8.
4. Hammer KA, *et al.* In vitro activity of *Melaleuca alternifolia* (tea tree) oil against dermatophytes and other filamentous fungi. *J Antimicrob Chemother* 2002; **50**: 195–9.
5. Satchell AC, *et al.* Treatment of dandruff with 5% tea tree oil shampoo. *J Am Acad Dermatol* 2002; **47**: 852–5.
6. Koh KJ, *et al.* Tea tree oil reduces histamine-induced skin inflammation. *Br J Dermatol* 2002; **147**: 1212–7.
7. Mozelis NB, *et al.* Immediate systemic hypersensitivity reaction associated with topical application of Australian tea tree oil. *Allergy Asthma Proc* 2003; **24**: 73–5.
8. Perrett CM, *et al.* Tea tree oil dermatitis associated with linear IgA disease. *Clin Exp Dermatol* 2003; **28**: 167–70.
9. Hammer KA, *et al.* Antifungal effects of *Melaleuca alternifolia* (tea tree) oil and its components on *Candida albicans*, *Candida glabrata* and *Saccharomyces cerevisiae*. *J Antimicrob Chemother* 2004; **53**: 1081–5.
10. Hammer KA, *et al.* A review of the toxicity of *Melaleuca alternifolia* (tea tree) oil. *Food Chem Toxicol* 2006; **44**: 616–25.
11. Carson CF, *et al.* Melaleuca alternifolia (Tea Tree) oil: a review of antimicrobial and other medicinal properties. *Clin Microbiol Rev* 2006; **19**: 50–62.

## Preparations

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

**Austral.:** Clean Skin Anti Acne; Rapaid Antiseptic; Rapaid Itch Relief; **Chile:** Acnoxyl Gel Cuidado Intensivo; Acnoxyl Gel De Limpieza; Acnoxyl Stick; Corrector; Sebolic; **Fr.:** Myleuca; **Israel:** Bumshield; **Malaysia:** MOOV; **Singapore:** Rapaid; **UK:** Bumshield Gel; Melair.

**Multi-ingredient:** **Arg.:** Aveno; **Austral.:** Apex Repel Natural; APR Cream; Clean Skin Face Wash; Curaderm; Neutralize; Rapaid Rash-Relief; SP Cream; VR; **Chile:** Acnoxyl Abrasivo; Acnoxyl Gel Humectante; Acnoxyl Jabon Liquido; Acnoxyl Jabon; Acnoxyl Locion Tonica; Acnoxyl

Shampoo Cabello Graso; **Fr.:** Cicatridine; Dermocica; Mycogel; Phytosq-ume; Squaphane P; **Hong Kong:** Mycogel; **Ital.:** Proctopure; **Malaysia:** T3 Acne; **NZ:** Apex Repel Natural; Electric Blue Headlice; Lice Blaster; **Singapore:** Burnaid; Rapaid; T3; Tinasolve; **Thai:** Fungicon; Gynecon-T; **UK:** Dr Johnsons Nit & Lice; Sinose; Skin Clear; Tea Tree & Witch Hazel Cream; Teenstick.

## Melanocyte-stimulating Hormone

B Hormone; Chromatophore Hormone; Intermedin; Intermedina; Melanotropin; MSH; Pigment Hormone.

CAS — 9002-79-3.

## Profile

Melanocyte-stimulating hormone is a polypeptide isolated from the pars intermedia of the pituitary of fish and amphibia which causes dispersal of melanin granules in the skin of fish and amphibia and allows adaptation to the environment.

In adult humans, the pituitary gland lacks a distinct intermediate lobe, and the pituitary is not thought to secrete melanocyte-stimulating hormone (MSH) directly. However, the precursor molecule, pro-opiomelanocortin, is cleaved in the pituitary into corticotropin (p.1523), the glycoprotein  $\beta$ -lipotrophin ( $\beta$ -LPH), and an amino-terminal peptide. Subsequent processing in other tissues, such as the brain and gastrointestinal tract, may yield three forms of MSH,  $\alpha$ -MSH (via corticotropin cleavage),  $\beta$ -MSH, and  $\gamma$ -MSH. The presence and function of these melanocyte-stimulating hormones in man are uncertain. A receptor analogous to that in amphibians is apparently lacking in humans; effects on skin pigmentation emanating from the pituitary are primarily mediated by corticotropin.

Release of melanocyte-stimulating hormone is inhibited in *animals* by melanostatin; there is also evidence for a hypothalamic releasing factor (MRF).

Melanocyte-stimulating hormone is under investigation, as  $\alpha$ -MSH, in the prevention and treatment of ischaemic intrinsic acute renal failure. A synthetic analogue of  $\alpha$ -MSH (4-L-norleucine-7-D-phenylalanine- $\alpha$ -MSH; melanotan-I) is under investigation as a stimulant of melatonin production for the prevention of sunburn.

## Melanostatin

Intermedin-inhibiting Factor; Melanocyte-stimulating-hormone-release-inhibiting Factor; Melanostatin; Melanotropin Release-inhibiting Factor; MIF; Pro-Leu-Gly-NH<sub>2</sub>.

CAS — 9083-38-9.

## Profile

Melanostatin is a tripeptide, obtained from the hypothalamus, that inhibits the release of melanocyte-stimulating hormone (see above) in *animals*. However, there is little evidence of its activity in man. It has been tried in the treatment of depression and parkinsonism but with little benefit.

## Melatonin

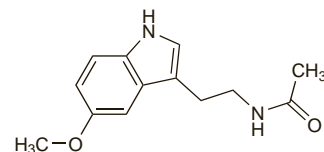
*N*-Acetyl-5-methoxytryptamine; Melatonini; Melatonina; Melatoninum. *N*-[2-(5-Methoxyindol-3-yl)ethyl]acetamide.

$C_{13}H_{16}N_2O_2 = 232.3$ .

CAS — 73-31-4.

ATC — N05CH01.

ATC Vet — QN05CH01.



## Profile

Melatonin is a hormone produced in the pineal gland from the amino acid tryptophan. Results mainly from *animal* studies indicate that melatonin increases the concentration of aminobutyric acid and serotonin in the midbrain and hypothalamus and enhances the activity of pyridoxal-kinase, an enzyme involved in the synthesis of aminobutyric acid, dopamine, and serotonin. Melatonin is involved in the inhibition of gonadal development and in the control of oestrus. It is also involved in protective changes in skin coloration. There appears to be a diurnal rhythm of melatonin secretion; it is secreted during hours of darkness and may affect sleep pattern. Because of its possible role in influencing circadian rhythm, melatonin has been tried in the alleviation of jet lag and other disorders resulting from delay of sleep. Doses of 2 mg given orally before bedtime are used in the short-term management of insomnia in patients aged 55 or over. Melatonin has also been studied in various depressive disorders including seasonal affective disorder, and in large doses for its contraceptive activity.

A number of melatonin analogues are being developed.

**Adverse effects.** An increase in seizure activity was noted in 4 of 6 children with severe neurological deficits during treatment with melatonin for sleep disorders.<sup>1</sup> Seizure activity returned to baseline values when melatonin was stopped and recurred on re-challenge.

- Sheldon SH. Pro-convulsant effects of oral melatonin in neurologically disabled children. *Lancet* 1998; **351**: 1254.

**Uses.** Melatonin has been tried in a number of disorders<sup>1</sup> including, in large doses, as an adjunct to conventional chemotherapy for malignant neoplasms<sup>2,3</sup> and, with norethisterone, as a contraceptive.<sup>4</sup> It is possible that contraceptive use of melatonin may be associated with a reduced risk of breast cancer.<sup>5</sup> For mention of response to melatonin in 2 patients with sarcoidosis, see p.1512. Preliminary studies have also suggested that melatonin may be beneficial in hyperlipidaemias,<sup>6</sup> cluster headaches,<sup>7</sup> tinnitus,<sup>8</sup> alopecia in women,<sup>9</sup> and irritable bowel syndrome associated with sleep disturbances.<sup>10</sup> Repeated bedtime doses may also play a part in reducing nocturnal blood pressure in patients with essential hypertension.<sup>11</sup> Claims for its value as an anti-ageing treatment and for use in conditions such as Alzheimer's disease and AIDS are unfounded.<sup>2,12</sup> The effects of long-term use of melatonin have yet to be assessed.

- Wetterberg L. Melatonin and clinical application. *Reprod Nutr Dev* 1999; **39**: 367–82.
- Pepping J. Melatonin. *Am J Health-Syst Pharm* 1999; **56**: 2520–7.
- Lissoni P, *et al.* Decreased toxicity and increased efficacy of cancer chemotherapy using the pineal hormone melatonin in metastatic solid tumour patients with poor clinical status. *Eur J Cancer* 1999; **35**: 1688–92.
- Short RV. Melatonin. *BMJ* 1993; **307**: 952–3.
- Cohen M, *et al.* Hypotheses: melatonin/steroid combination contraceptives will prevent breast cancer. *Breast Cancer Res Treat* 1995; **33**: 257–64.
- Pittalis S, *et al.* Effect of a chronic therapy with the pineal hormone melatonin on cholesterol levels in idiopathic hypercholesterolemic patients. *Recent Prog Med* 1997; **88**: 401–2.
- Leone M, *et al.* Melatonin versus placebo in the prophylaxis of cluster headache: a double-blind pilot study with parallel groups. *Cephalalgia* 1996; **16**: 494–6.
- Rosenberg SI, *et al.* Effect of melatonin on tinnitus. *Laryngoscope* 1998; **108**: 305–10.
- Fischer TW, *et al.* Melatonin increases anagen hair rate in women with androgenetic alopecia or diffuse alopecia: results of a pilot randomized controlled trial. *Br J Dermatol* 2004; **150**: 341–5.
- Song GH, *et al.* Melatonin improves abdominal pain in irritable bowel syndrome patients who have sleep disturbances: a randomised, double blind, placebo controlled study. *Gut* 2005; **54**: 1402–7.
- Scheer FAJL, *et al.* Daily nighttime melatonin reduces blood pressure in male patients with essential hypertension. *Hypertension* 2004; **43**: 192–7.
- Brzezinski A. Melatonin in humans. *N Engl J Med* 1997; **336**: 186–95.

**INSOMNIA.** Although melatonin is considered<sup>1–6</sup> to be potentially useful in the management of various forms of insomnia (p.957), especially those associated with circadian rhythm disturbances, there is little evidence of efficacy from large studies and its long-term safety remains to be established. A meta-analysis<sup>7</sup> of randomised controlled studies concluded that melatonin does not have a significant effect on sleep onset latency in secondary sleep disorders or those accompanying sleep restriction such as jet lag and shift work. In healthy subjects melatonin has been reported<sup>8,9</sup> to reduce the time to onset of sleep and to increase the time spent asleep. Whether this is due to adjustment of the 'body clock' or any hypnotic action of melatonin is unclear. Measurement of nocturnal urinary excretion of the major metabolite, 6-sulfatoxymelatonin, demonstrated that low nocturnal melatonin production is associated with insomnia in patients over 55 years of age, and might identify those more likely to respond to treatment with melatonin.<sup>10</sup> Improved quality of sleep has been reported in elderly patients treated with melatonin for insomnia,<sup>11</sup> and it might be of use in delayed sleep phase syndrome<sup>12</sup> and insomnia in shift workers and totally blind people, although some<sup>13,14</sup> have found no beneficial effects of melatonin in night shift workers or emergency medicine employees. There has also been a report<sup>15</sup> of a patient with somnolence associated with melatonin deficiency after pinealectomy who responded to treatment with melatonin. A preliminary report<sup>16</sup> has suggested that use of melatonin may enable benzodiazepine therapy for insomnia to be stopped without impairing the quality of sleep. However, melatonin might adversely affect sleep patterns in some circumstances.<sup>17</sup>

- Haimov I, Lavie P. Potential of melatonin replacement therapy in older patients with sleep disorders. *Drugs Aging* 1995; **7**: 75–8.
- Brown GM. Melatonin in psychiatric and sleep disorders: therapeutic implications. *CNS Drugs* 1995; **3**: 209–26.
- Anonymous. Melatonin. *Med Lett Drugs Ther* 1995; **37**: 111–12.
- Arendt J. Melatonin. *BMJ* 1996; **312**: 1242–3.
- Lamberg L. Melatonin potentially useful but safety, efficacy remain uncertain. *JAMA* 1996; **276**: 1011–14.
- Skene DJ, *et al.* Use of melatonin in the treatment of phase shift and sleep disorders. *Adv Exp Med Biol* 1999; **467**: 79–84.

- Buscemi N, *et al.* Efficacy and safety of exogenous melatonin for secondary sleep disorders and sleep disorders accompanying sleep restriction: meta-analysis. Abridged version: *BMJ* 2006; **332**: 385–8. Full version: <http://www.bmj.com/cgi/reprint/332/7538/385> (accessed 25/07/08)
- Zhdanova IV, *et al.* Sleep-inducing effects of low doses of melatonin ingested in the evening. *Clin Pharmacol Ther* 1995; **57**: 552–8.
- Attenburrow MEJ, *et al.* Low dose melatonin improves sleep in middle-aged subjects. *Psychopharmacology (Berl)* 1996; **126**: 179–81.
- Leger D, *et al.* Nocturnal 6-sulfatoxymelatonin excretion in insomnia and its relation to the response to melatonin replacement therapy. *Am J Med* 2004; **116**: 91–5.
- Garfinkel D, *et al.* Improvement of sleep quality in elderly people by controlled-release melatonin. *Lancet* 1995; **346**: 541–4.
- Nagtegaal JE, *et al.* Effects of melatonin on the quality of life in patients with delayed sleep phase syndrome. *J Psychosom Res* 2000; **48**: 45–50.
- Wright SW, *et al.* Randomized clinical trial of melatonin after night-shift work: efficacy and neuropsychological effects. *Ann Emerg Med* 1998; **32**: 334–40.
- Jockovich M, *et al.* Effect of exogenous melatonin on mood and sleep efficiency in emergency medicine residents working night shifts. *Acad Emerg Med* 2000; **7**: 955–8.
- Lehmann ED, *et al.* Somnolence associated with melatonin deficiency after pinealectomy. *Lancet* 1996; **347**: 323.
- Garfinkel D, *et al.* Facilitation of benzodiazepine discontinuation by melatonin: a new clinical approach. *Arch Intern Med* 1999; **159**: 2456–60.
- Middleton BA, *et al.* Melatonin and fragmented sleep patterns. *Lancet* 1996; **348**: 551–2.

**JET LAG.** Melatonin has been reported to alleviate jet lag following long flights.<sup>1–4</sup> The most appropriate dosing schedule has yet to be determined but will depend on both the direction of travel and the distance travelled. A systematic review<sup>5</sup> concluded that melatonin was effective in preventing or reducing jet lag in those travelling across 5 or more time zones, particularly in an easterly direction, and especially if jet lag had been experienced previously; travellers crossing 2 to 4 time zones might also derive benefit. However, a meta-analysis<sup>6</sup> of randomised controlled studies concluded that melatonin does not have a significant effect on sleep onset latency accompanying jet lag.

- Waterhouse J, *et al.* Jet-lag. *Lancet* 1997; **350**: 1611–16.
- Arendt J. Jet-lag. *Lancet* 1998; **351**: 293–4.
- Arendt J. Jet-lag and shift work: (2) therapeutic use of melatonin. *J R Soc Med* 1999; **92**: 402–5.
- Waterhouse J, *et al.* Jet lag: trends and coping strategies. *Lancet* 2007; **369**: 1117–29.
- Herxheimer A, Petrie KJ. Melatonin for the prevention and treatment of jet lag. Available in The Cochrane Database of Systematic Reviews; Issue 2. Chichester: John Wiley; 2002 (accessed 28/04/05).
- Buscemi N, *et al.* Efficacy and safety of exogenous melatonin for secondary sleep disorders and sleep disorders accompanying sleep restriction: meta-analysis. Abridged version: *BMJ* 2006; **332**: 385–8. Full version: <http://www.bmj.com/cgi/reprint/332/7538/385> (accessed 25/07/08)

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**Arg:** Armonil Noche; Buenas Noches (Melaoli; NochiX; Repentil); **Chile:** Novej; **Hong Kong:** Melapure; **Hung:** Bio-Melatonin; **India:** Meloset; **Mex:** Benedorm; Cronocaps; Revonox; **Port:** Circadin; **Rus:** Melaxen (Мелаксен); **UK:** Circadin; **USA:** Transzone.

**Multi-ingredient:** **Arg:** Plenovit Melatonina; **India:** Eternex; Stresnil; **USA:** Bevitamel; Melaegic PM.

## Melilot

Barküno žolė; Gelber Steinklee; Komonicová nat'; Mélilot; Meliloti herba; Rohtomesikkä; Sötväpling; Sweet Clover; Yellow Melilot; Yellow Sweet Clover; Ziele nostrzyka.

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

**Ph. Eur. 6.2** (Melilot; Meliloti Herba). The whole or cut, dried aerial parts of *Melilotus officinalis*. It contains a minimum of 0.3% coumarin, calculated with reference to the dried drug. Protect from light.

## Profile

Melilot is used internally in herbal preparations for chronic venous insufficiency. It contains coumarin (see p.2288) and its derivatives and the dose may be expressed in terms of coumarin. The German expert committee for herbal drugs and preparations (Commission E) also allows the addition or substitution of *M. altissimus* (tall melilot), tall yellow sweet clover.

Melilotus officinalis is also used externally.

**Homeopathy.** Melilot has been used in homeopathic medicines under the following names: Melilotus officinalis; Mel. off.

## Preparations

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

**Braz:** Vecasten; **Ger:** Meli Rephastan.

**Multi-ingredient:** **Arg:** Snell Patch; Snell Progress; **Austral:** Bioglan Zelleulean with Escin; **Chile:** Celltech Gold; **Fr:** Antinerveux Lessourd; Creme au Melilot Composee; Cyclo 3; Ditavene; Esberiven; Esberiven Fort; Evarese; Sedopal; **Ger:** Phlebotrid N; Salus Venen Krauter Dragees N; Venen Krauter Nt; **Ita:** Capill Venogel; Dermilia Flebozin; Diosmina Complex; Facosmina; Flebo-St; Flebofort; Levital Plus; Lipaven; Pulsalux; RepaVen; Venodin; Venoton; **Rus:** Cyclo 3 (Цикло 3); **Singapore:** Cyclo 3; **Spain:** Fabroven; Venofit; **Switz:** Phlebotrid; Veino-Gouttes-Nt.

## Melissa

Citromfűlevél; Lemon Balm; Liść melisy; Meduřkový list; Melisa; Meliss; Melissae folium; Mélisse, feuille de; Melissenblatt; Melisų lapai; Sitruunamelissanlehti.

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

**Ph. Eur. 6.2** (Melissa Leaf). The dried leaf of *Melissa officinalis*. It contains not less than 4% of total hydroxycinnamic derivatives expressed as rosmarinic acid (C<sub>18</sub>H<sub>16</sub>O<sub>8</sub> = 360.3), calculated with reference to the dried drug. It has an odour reminiscent of lemon. Protect from light.

## Profile

Melissa has been used as a carminative and sedative. It is an ingredient of herbal remedies used for a variety of disorders. It is also reported to have virustatic activity. The chief constituent of melissa is citral (p.2284). Hypersensitivity reactions to melissa have been reported.

Melissa is the source of melissa oil (see below).

**Homeopathy.** Melissa has been used in homeopathic medicines under the following names: Melissa officinalis.

## References

- Ballard CG, *et al.* Aromatherapy as a safe and effective treatment for the management of agitation in severe dementia: the results of a double-blind, placebo-controlled trial with melissa. *J Clin Psychiatry* 2002; **63**: 553–8.

## Preparations

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

**Austria:** Balm-Mint; Lomaherpan; **Belg:** Dormiplant; **Chile:** Citromel; **Cz:** Lakina; Lomaherpan; Medovka Leksarska; Medunkovy, Medunkova; **Ger:** Gastrovegetal; Lomaherpan; Me-Sabona; Sedinfant; **Rus:** Novo-Passit (Ново-Пассит); **Switz:** Valverde Boutons de fleur creme.

**Multi-ingredient:** **Arg:** Dr Calm; Erbona Noche; Nervocalm; Sedante Arcel; Valeriana Oligoplex; Valeriana Relax Diates; **Austral:** Natural Deep Sleep; **Austria:** Abdomilon N; Baldrain; Euekan; Manazeller; Passedan; Passely; Sedogelat; Songha; Species nervinae; The Chambard-Tee; Wechseltel St Severn; **Belg:** Minhaz; Songha; **Braz:** Anevrax; Balsamo Branco; Calmapax; Camomila; Elxir de Passiflora; Passaneuro; Passilex; Sonhare; **Canad:** Herbal Sleep Well; Natural HRT Nighttime; **Chile:** Melipass; Recalm; **Cz:** Abdomilon; Alvisan Neo; Baldrain; Blahungstee Nt; Eugastrin; Euekan; Fytokliman Planta; Hertz- und Kreislauftee; Hypotonica; Ibergast; Klosterfrau Melisana; Melaton; Nervova Cajova Smes; Nontusy; Novo-Passit; Passedan; Persen; Schlaf-Nervette Nt; Senalax; Songha Night; Species Nervinae Planta; Valofyt Neo; **Fr:** Bio-card; Dystolise; Elxir Bonjean; Mediflor Tisane Calmante Troubles du Sommeil No 14; Mediflor Tisane Circulation du Sang No 12; Vagostabyl; **Ger:** Abdomilon N; Baldrain N Stark; Doppelherz Melissegeist; Dormarist; Dr Scheffer Bergischer Krauttee Nerven- und Beruhigungstee; Euegal; Euegal Entspannungs- und Einschlafdragees; Euegal Entspannungs- und Einschlafotropen; Gastrol St; Gutnacht; Heumann Beruhigungstee Teneval; Ibergast; JuDorm; Jukunda Melissen-Krautergeist Nt; Lindofluid N; Me-Sabona plus; Melissegeist; Nervosana; Oxacant Nt; Oxacant-sedativ; Pascesodon; Phytonoct; Plantival novo; Presselin Blahungs K 4 Nt; Pronervon Phytol; RubieSed; Schlaf- und Nerventee; Seda-Plantina; Sedacur; Sedariston; Sedasyx; Sedinfant Nt; Stullmaton; **Hung:** Euekan; Sedacur; **Israel:** Songha Night; **Ital:** Actenacal; Calmason; Colmil; Dormiplant; Emmenoiasi; Melissa (Specie Composita); Sedatol; Tisana Klemata; Vagostabil; Valeriana (Specie Composita); **Malaysia:** Circarol; **Mex:** Nordimenty; Plantival; **NZ:** Botanica Hayfever; Mr Nits; **Philipp:** Circulan; **Pol:** Amarosal; Aromatol; Calmina; Carmolis; Cravisol; Dormiplant; Klimax; Lumeval; Melisal; Melisana Klosterfrau; Melissid; Nervinolon; Nervonix; Nervosol; Nervobonisol; Perforat; Persen; Psychotonisol; Relana; Sedomix; **Port:** Erpecalm; Songha; **Rus:** Doppelherz Melissa (Доппельгерц Мелисса); Doppelherz Vitalotonic (Доппельгерц Виталотоник); Persen (Персен); **S.Afr:** Melissegeist; Spiritus Contra Tus-sim Drops; **Spain:** Agua del Carmen; Caramelos Agua del Carmen; Dormiplant; Himelan; Jaquesor; Melival; Mesatit; Natusor Aerofane; Natusor Jaquesant; Nervikan; Relana; Resolutivo Regium; Solucion Schoum; **Switz:** Alcolat de Melisse; Arterosan plus; Baldrain; Baldrisedon plus; Cardialforce; Carmol; Dormiplant; Dragees pour la detente nerveuse; Gastrosan; Hyperforce comp; Ibergast; Phytonmed Nervo; Relaxane; Relaxo; Songha Night; Soporin; Tisane calmante pour les enfants; Tisane favorisant l'allaitement; Tisane pour l'estomac; Tisane pour le coeur et la circulation; Tisane pour le sommeil et les nerfs; Tisane pour nourissons et enfants; Tisane relaxante Nt; Valverde Detente dragees; Valviska; **UK:** Melissa Comp; Valeriana Day Time; Valeriana Night-Time; **Venez:** Euekan; Sedival.

## Melissa Oil

Balm Oil; Esencia de Melisa; Lemon Balm Oil.

CAS — 8014-71-9.

## Profile

Melissa oil is the essential oil obtained from melissa (*Melissa officinalis*), above. It is used in preparations with other essential oils in a variety of disorders. It is also used in aromatherapy.

## Preparations

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

**Multi-ingredient:** **Austria:** Opino; **Chile:** Agua del Carmen; Agua Melisa Carminativa; **Cz:** Thrombocid; **Fr:** Stomargil; **Ger:** Amol Heilkräutergeist N; Cor>Select; Thrombocid; **Gr:** Opino-jel; **Indon:** Opino; **Ital:** Dentosan Azione Intensiva; Dentosan Mese; Neuralta Migren; **Pol:** Amol; Argol Essenza Balsamica; Argol Grip; Argol Rheuma; **Port:** Thrombocid; **Switz:** Anal-Gen; Thrombocid.