

Preparations

Proprietary Preparations (details are given in Part 3)

Austral: Mederma; **Chile:** Mederma†; **Israel:** Mederma; **Malaysia:** Mederma; **Pol:** Alcep; **Singapore:** Mederma; **USA:** Mederma.

Multi-ingredient: **Arg:** Contractubex; **Austral:** Garlic Allium Complex; **Austria:** Contractubex; **Braz:** Contractubex; **Cz:** Contractubex; **Ger:** Contractubex; **Hong Kong:** Contractubex; **Hung:** Contractubex; **India:** Contractubex; **Indon:** Mederma; **Ital:** Skarifix; **Malaysia:** Palmer's Cocoa Butter Formula Scar Serum; **Philipp:** Contractubex; **Pol:** Alcepan; Capan; Cepasme; Cepastil; **Contractubex; Rus:** Contractubex (Контрактубекс); **Singapore:** Erase; **Switz:** Contractubex.

Ononis

Arrête-Boeuf; Bugrane, racine de; Busktörnerot; Dirvenij šaknys; Gatuña; Hauhechelwurzel; Jehlicový kořen; Ononidis radix; Piikkiorakonjuuri; Racine de Bugrane; Radix Ononidis; Restharrow Root; Spiny Restharrow; Tövösiglice-gyökér.

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

Ph. Eur. 6.2 (Restharrow Root). The whole or cut, dried root of *Ononis spinosa*.

Profile

Ononis has diuretic activity. It has been used in herbal preparations for the treatment of oedema, urinary-tract disorders, rheumatic disorders, and constipation.

Preparations

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Multi-ingredient: **Austria:** Krauter Hustensaft; Nierentee St Severin; Uropurat; **Cz:** Nephrosal†; Species Diureticae Planta†; Species Urologicae Planta; Stoffwechselltee N†; Urologicka Cajova Smes; **Fr:** Depuratum; Schoum; **Ger:** Alasenn; Aqualibar; Hevert-Blasen-Nieren-Tee N; Hewerberel-Tee; nephro-loges; Nephronorm med†; Nephroselect M; Nephrobin-N†; Nieren Blasen- und Nieren-Tee V†; Nieren-Tee N†; Presseln Nieren-Blasen K 3†; Renob Blasen- und Nierentee; Uvirgan N†; **Ital:** Gramigna (Specie Composita)†; Soluzione Schoum; **Pol:** Betasol; Diuronis; **Rus:** Herbin Urological Drops (Гербин Урологические Капли); **Switz:** Demonatur Dragees pour les reins et la vessie; Nephrosolid; Phytomed Nephro†; Prosta-Caps Chassot N.

Bitter Orange

Aurantii amari flos (bitter-orange flower); Aurantii Amari Pericarpium (bitter orange fruit); Bigaradier; Karčavaisių citrinmedžių žiedai (bitter-orange flower); Keserű narancs virág (bitter-orange flower); Květ hořkého pomeranče (bitter-orange flower); Naranja Amarga; Naranja amarga, corteza de; Oranger amer, fleur d' (bitter-orange flower); Owocnia pomarańczy gorzkiej (bitter orange fruit); Pomeransblomma (bitter-orange flower); Pomeranssinkukka (bitter-orange flower); Pomeranze; Seville Orange.

Апельсин; Померанец

Pharmacopoeias. *Eur.* includes the dried peel and flowers. *Jpn* includes the peel.

Ph. Eur. 6.2 (Bitter-orange Epicarp and Mesocarp; Aurantii amari epicarpium et mesocarpium; Dried Bitter-orange Peel BP 2008). The dried epicarp and mesocarp of the ripe fruit of *Citrus aurantium*, partly freed from the white spongy tissue of the mesocarp and endocarp, containing a minimum of 2.0% v/v of essential oil, calculated with reference to the anhydrous drug. It has an aromatic odour and a spicy bitter taste.

Ph. Eur. 6.2 (Bitter-orange Flower; Aurantii amari flos). The whole, dried, unopened flower of *C. aurantium* subsp. *aurantium* containing a minimum of 8.0% of total flavonoids, expressed as naringin (C₂₇H₃₂O₁₄ = 580.5), calculated with reference to the dried drug.

Profile

The dried peel of the bitter orange, *Citrus aurantium* subsp. *aurantium* (*Citrus aurantium* subsp. *amara*) (Rutaceae) is used as a flavour and for its bitter and carminative properties. An essential oil is prepared from fresh bitter-orange peel (bitter-orange oil) and is similar to sweet orange oil (p.2357). Both bitter-orange oil and petitgrain bigarade oil (prepared from the leaves and twigs) are used in aromatherapy.

The flowers are an ingredient of herbal remedies used for nervous and sleep disorders. Bitter-orange flower is the source of Neroli Oil (p.2351).

The whole dried immature fruit is used similarly to the dried peel. In Chinese medicine, the dried immature fruits are known as zhi shi and zhi qiao.

Photosensitivity is associated with citrus oils.

Action and use. *Citrus aurantium* was one of the most frequently used herbal remedies in Puerto Rico.¹ Indications included sleep disorders, gastrointestinal disorders, respiratory ailments, and raised blood pressure.

The volatile oil of dried bitter-orange peel has shown antifungal activity.²

Bitter-orange extract has been added to herbal weight loss remedies as it contains the sympathomimetic synephrine (a name that has been used for both phenylephrine and oxedrine), which is claimed to increase metabolism and promote thermogenesis, although efficacy is not proven. Variant angina³ and ischaemic colitis⁴ have been reported in patients taking dietary supplements containing bitter orange, and reports of serious cardiovascular

adverse effects possibly associated with the synephrine content of bitter orange present in such preparations have been received in Canada.^{5,6} Raised systolic and diastolic blood pressure and heart rate were seen after ingestion of a proprietary bitter orange preparation in one small randomised placebo-controlled crossover study.⁷ However, in a similar study⁸ comparing a single-ingredient bitter orange preparation with a combination preparation, adverse haemodynamic effects appeared to be related to the additional presence of other possible stimulants such as caffeine, rather than directly proportional to the dose of bitter orange alone.

- Hernández L, et al. Use of medicinal plants by ambulatory patients in Puerto Rico. *Am J Hosp Pharm* 1984; **41**: 2060-4.
- Ramadan W, et al. Oil of bitter orange: new topical antifungal agent. *Int J Dermatol* 1996; **35**: 448-9.
- Gange CA, et al. Variant angina associated with bitter orange in a dietary supplement. *Mayo Clin Proc* 2006; **81**: 545-8.
- Sultan S, et al. Ischemic colitis associated with use of a bitter orange-containing dietary weight-loss supplement. *Mayo Clin Proc* 2006; **81**: 1630-1.
- Health Canada. Products containing bitter orange or synephrine: suspected cardiovascular adverse reactions. *Can Adverse React News* 2004; **14** (4): 3-4. Also available at: http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/medeff/carn-bcei_v14n4-eng.pdf (accessed 06/08/08)
- Health Canada. Bitter orange or synephrine: update on cardiovascular adverse reactions. *Can Adverse React News* 2007; **17** (2): 2-3. Also available at: http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/medeff/carn-bcei_v17n2-eng.pdf (accessed 06/08/08)
- Bui LT, et al. Blood pressure and heart rate effects following a single dose of bitter orange. *Ann Pharmacother* 2006; **40**: 53-7.
- Haller CA, et al. Hemodynamic effects of ephedra-free weight-loss supplements in humans. *Am J Med* 2005; **118**: 998-1003.

Preparations

BP 2008: Concentrated Compound Gentian Infusion; Concentrated Orange Peel Infusion; Orange Peel Infusion; Orange Syrup; **Ph. Eur.:** Bitter-Orange-Epicarp and Mesocarp Tincture.

Proprietary Preparations (details are given in Part 3)

Ger: Carvomin Magentropfen mit Pomeranze†.

Multi-ingredient: **Arg:** Calmtabs†; Hepatodirectol; **Austria:** China-Eisenwein; Eicebaer; Ferrovin-Chinaeisenwein; Mariazeller; Montana; Sigman-Haustropfen; St Bonifatius-Tee; Tussimont; **Canad:** Biotrim†; **Cz:** Klosterfrau Melissa; Naturland Grosser Swedenbitter†; Pleumolysin; Schlaf-Nerventee N†; **Fr:** Calmophytum; Elixir Bojean; Elixir Grez†; Mediflor Tisane Calmante Troubles du Sommeil No 14; Quintonine; Vegetoserum; **Ger:** Carminativum-Hetterich; Doppelherz Melissengeist†; Gallexir; Gastrocur†; Montana N; Sedovent; **Hong Kong:** LEAN Formula w/ Advantra†; **India:** Toniazol†; **Indon:** Jesscool; **Israel:** Passiflora; **Ital:** Assenzio (Specie Composita)†; Gastro-Pepsin; Genziana (Specie Composita)†; Valeriana (Specie Composita)†; **Pol:** Herbaton; Kropke Zoladkowie; Gallexir; Doppelherz Melissa (Доппельгерц Мелисса); Original Grosser Bittner Balsam (Оригинальный Большой Бальзам Биттнера); **S.Afr:** Versterkdruppels; **Singapore:** Chitosano; **Spain:** Euzymina Lisina I; Euzymina Lisina II; Jaquesort†; Natuser Jaquesant†; Sedonat; **Switz:** Pastilles pectorales Demo N; Phytomed Nervoj; Tisane calmante pour les enfants; Tisane pour le sommeil et les nerfs; **UK:** Vital Eyes.

Sweet Orange

Naranja.

Pharmacopoeias. *Chin.* includes both the dried immature fruit of *Citrus aurantium* and its cultivated varieties and the dried young fruit of *C. aurantium*. *Swiss* includes the ripe fresh fruit of *Citrus sinensis*.

Profile

Sweet orange, *Citrus sinensis* (*Citrus aurantium* var. *dulcis*) (Rutaceae), is an ingredient of herbal remedies used for nervous and sleep disorders. The peel is the source of sweet orange oil (below). Citrus fruits are a source of vitamin C (p.1983).

Photosensitivity is associated with citrus oils.

Preparations

USNF 26: Orange Syrup; Sweet Orange Peel Tincture.

Proprietary Preparations (details are given in Part 3)

Multi-ingredient: **Austria:** Expectal-Tropfen; Magentee St Severin; Mariazeller; **Cz:** Passedan; **Ger:** Majoramin forte†; **Rus:** Original Grosser Bittner Balsam (Оригинальный Большой Бальзам Биттнера).

Sweet Orange Oil

Apelsininių citrinmedžių vaisių žievelių eterinis aliejus; Apelsinolja; Appelsininkuoriöljy; Arancia Dolce Essenza; Aurantii dulcis aetheroleum; Aurantii Dulcis Pericarpium Etheroleum; Essence of Orange; Essence of Portugal; Essência de Laranja; Naranja, aceite esencial de; Orange douce, huile essentielle d'; Orange Oil; Silice opłody słodkiego pomarańcze.

NOTE. The oil from the flowers of *Citrus aurantium* var. *amara* is known as neroli oil or orange flower oil (p.2351).

Pharmacopoeias. In *Eur.* (see p.vii) and *Jpn.* Also in *USNF*. **Ph. Eur. 6.2** (Sweet Orange Oil). An essential oil obtained without heating, by suitable mechanical treatment from the fresh peel of the fruit of *Citrus sinensis* (*Citrus aurantium* var. *dulcis*). A suitable antioxidant may be added. It contains 0.4 to 0.6% α -pinene, 0.02 to 0.3% β -pinene, 0.2 to 1.1% sabinene, 1.7 to 2.5% β -myrcene, 92.0 to 97.0% limonene, 0.1 to 0.4% octanal, 0.1 to 0.4% decanal, 0.2 to 0.7% linalol, 0.02 to 0.10% neral, 0.02 to 0.5% valencene, and 0.03 to 0.02% geranial.

A clear, pale yellow to orange, mobile liquid, which may become

cloudy when chilled. It has a characteristic odour of fresh orange peel. Relative density 0.842 to 0.850. Store in well-filled airtight containers at a temperature not exceeding 25°. Protect from light.

USNF 26 (Orange Oil). The volatile oil obtained by expression from the fresh peel of the ripe fruit of *Citrus sinensis* (Rutaceae), containing not less than 1.2% w/v and not more than 2.5% w/v of aldehydes, calculated as decanal (C₁₀H₂₀O = 156.3). It may be California-type or Florida-type orange oil. Store in well-filled airtight containers.

Profile

Sweet orange oil is used as a flavour, in perfumery, and in aromatherapy. It is used in the preparation of terpeneless orange oil. Photosensitivity reactions have been reported with citrus oils.

Preparations

USNF 26: Compound Orange Spirit.

Proprietary Preparations (details are given in Part 3)

Multi-ingredient: **Cz:** Coldastop; **Ger:** GeloStin; **Hong Kong:** Mages-to; **Switz:** Perskindol Classic; Pinimenthol†; Sansilla; Sibrovita; **Thai:** Magesto.

Terpeneless Orange Oil

Naranja sin terpeno, aceite esencial de; Oleum Aurantii Deterpenatum.

Pharmacopoeias. In *Br.*

BP 2008 (Terpeneless Orange Oil). A clear yellow or orange-yellow liquid, visibly free from water, with the odour and taste of orange, prepared by concentrating orange oil under reduced pressure until most of the terpenes have been removed, or by solvent partition. It contains not less than 18% w/v of aldehydes calculated as decanal (C₁₀H₂₀O = 156.3). Soluble 1 in 1 of alcohol (90%). Store in well-filled containers at a temperature not exceeding 25°. Protect from light.

Profile

Terpeneless orange oil consists chiefly of the free alcohols (+)-linalol and (+)-terpineol. It is used as a flavour. It is stronger in flavour and more readily soluble than the natural oil. Photosensitivity is associated with citrus oils.

Preparations

BP 2008: Compound Orange Spirit.

Orazamide (rINN)

AICA Orotate; Orazamide; Orazamidum; Oroxamide. 5-Aminoimidazole-4-carboxamide orotate dihydrate.

Оразамид

C₉H₁₀N₄O₅·2H₂O = 318.2.

CAS — 2574-78-9 (anhydrous orazamide); 60104-30-5 (orazamide dihydrate).

Profile

Orazamide has been given orally in the treatment of liver disorders.

Preparations

Proprietary Preparations (details are given in Part 3)

Port: Aicamin.

Multi-ingredient: **Port:** Oraica†.

Orchis Mascula

Early Purple Orchid.

Ятрышник Мужской

Profile

Orchis mascula, which is alleged to have aphrodisiac properties, has been used in herbal preparations for male sexual disorders.

Salep, a flour made from the dried ground tubers of *Orchis mascula* and various other species of orchid, contains a nutritious mucilage called bassorin; ice-cream made from salep is a great delicacy in Turkey.

Preparations

Proprietary Preparations (details are given in Part 3)

Multi-ingredient: **Rus:** Speman (Спеман); Speman Forte (Спеман Форте); Tentex (Тентекс).

Oregano

Dost; Origan; Origan herba; Origan Vulgaris Herba; Wild Marjoram.

CAS — 8007-11-2 (origanum oil).

NOTE. Distinguish from Marjoram, p.2337

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

Ph. Eur. 6.2 (Oregano). The dried leaves and flowers, separated from the stems, of *Origanum onites* or *O. vulgare* subsp. *hirtum*, or a mixture of both species. It contains a minimum of 2.5% w/v of essential oil, which contains a minimum of 60% of carvacrol and thymol, calculated with reference to the anhydrous drug. Protect from light.

The symbol † denotes a preparation no longer actively marketed