

**Homoeopathy.** Drosera has been used in homoeopathic medicines under the following names: Drosera rotundifolia; Dros rot.

### Preparations

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

**Ger.:** Makatussin Saft; Drosera†; Makatussin Tropfen Drosera†.

**Multi-ingredient:** **Austral.:** Asa Tones; **Austria:** Pilka; Pilka Forte; **Belg.:** Saintbois; **Chile:** Fitotos; Gotas Nican†; Notosil†; Pectoral Pasteur; Pulmagol; Ramistos; Sedotus†; **Cz.:** Bronchicum Pflanzlicher Hustenstiller†; Stodal; Tussilen; **Fr.:** Pastilles Monleou; Tussidoron; **Ger.:** Bronchicum Pflanzlicher†; Drosithym-N; Lomalt†; Makatussin Tropfen forte†; Tussiflorin Hustenstiller†; **Indon.:** Silex; **Israel:** Pilka; **Mex.:** Citos; Fen-y-Tos; **Port.:** Broncodiazina; Pilka; F†; **S.Afr.:** Cough Elixir; **Spain:** Broncovital†; Pazbronqual; Pilka; **Switz.:** Bromocod N; Bronchofluid N†; Demo Elixir pectoral N; Demo Tussil; Dragees S contre la toux†; Drosinula†; Escotussin; Famel; Gouttes contre la toux "S"; Makaphyt Gouttes antitussives; Makaphyt Sirop; Nican; Pastilles bronchiques S nouvelle formule; Pastilles pectorales Demo N; Pilka†; Sirop pectoral contre la toux S; Sirop S contre la toux et la bronchite; Thy-mo-drosin N†; Tussanil Compositum†; **Venez.:** Codebromil; Dromil Saucio; Pi-Fedrin.

### Drotaverine (rINN)

Drotaverina; Drotavérine; Drotaverinum. 1-(3,4-Diethoxybenzylidene)-6,7-dithoxy-1,2,3,4-tetrahydroisoquinoline.

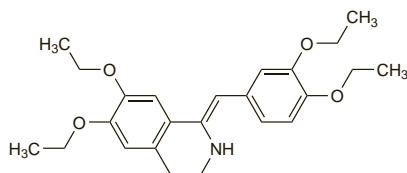
Дротаверин

$C_{22}H_{31}NO_4 = 397.5$ .

CAS — 14009-24-6 (drotaverine); 985-12-6 (drotaverine hydrochloride).

ATC — A03AD02.

ATC Vet — QA03AD02.



**Pharmacopoeias.** *Pol.* includes Drotaverine Hydrochloride.

### Profile

Drotaverine is used as an antispasmodic in the management of biliary-tract, urinary-tract, and gastrointestinal spasm, in usual oral doses of 120 to 240 mg daily in divided doses. It has also been given by intramuscular or intravenous injection.

### References

- Bolaji OO, *et al.* Pharmacokinetics and bioavailability of drotaverine in humans. *Eur J Drug Metab Pharmacokinet* 1996; **21**: 217–21.
- Romics I, *et al.* The effect of drotaverine hydrochloride in acute colicky pain caused by renal and ureteric stones. *BJU Int* 2003; **92**: 92–6.
- Singh KC, *et al.* Drotaverine hydrochloride for augmentation of labor. *Int J Gynaecol Obstet* 2004; **84**: 17–22.

**Porphyria.** Drotaverine has been associated with acute attacks of porphyria and is considered unsafe in porphyric patients.

### Preparations

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

**Arg.:** Proconil†; **Cz.:** No-Spa; **Hung.:** No-Spa; **India:** Drotin; Drovera†; **DVN:** Malaysia; No-Spa; **Philipp.:** No-Spa; **Pol.:** Galospa; No-Spa; **Rus.:** Везпа (Беспа); No-Spa (Но-Шпа); Срасовин (Спаковин); Срасмол (Спазмо); Срасоверин (Спазоверин); **Thai:** D-Tarin†; Deolin; No-Spa; Spablock; Срасовин; Спарах; Спарта; Toverine.

**Multi-ingredient:** **Cz.:** Quarelin†; **Hung.:** Algoflex-M; Algopyrin Complex; No-Spalgin; Paniverin; Quarelin; **Rus.:** No-Spalgin (Но-Шпалгин).

### Dulcamara

Bittersüß; Bittersweet; Douce-Amère; Dulcamarae Caulis; Woody Nightshade.

### Profile

Dulcamara consists of the dried stems and branches of *Solanum dulcamara* (Solanaceae). It was formerly a popular remedy for chronic rheumatism and skin eruptions and was given as an infusion.

All parts of the plant are poisonous due to the presence of solanaceous alkaloids. The berries have caused poisoning in children. Adverse effects are treated as described under Atropine, p.1220.

**Homoeopathy.** Dulcamara has been used in homoeopathic medicines under the following names: Solanum dulcamara; Dulc.

### Preparations

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

**Ger.:** Cefabene; Solapsor†.

**Multi-ingredient:** **Austria:** Dermatodoron; **Ger.:** Dermatodoron; **S.Afr.:** Cough Elixir; Dermatodoron.

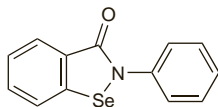
### Ebselen (rINN)

DR-3305; Ebselène; Ebseleno; Ebselenium; PZ-51. 2-Phenyl-1,2-benziselenazol-3-one.

Эбселеп

$C_{13}H_9NOSe = 274.2$ .

CAS — 60940-34-3.



### Profile

Ebselen has antioxidant activity and inhibits lipid peroxidation. It has been investigated as a neuroprotectant in stroke.

### References

- Yamauchi T, *et al.* Ebselen in acute ischemic stroke: a placebo-controlled, double-blind clinical trial. *Stroke* 1998; **29**: 12–17.
- Saito I, *et al.* Neuroprotective effect of an antioxidant, ebselen, in patients with delayed neurological deficits after aneurysmal subarachnoid hemorrhage. *Neurosurgery* 1998; **42**: 269–78.

### Echinacea

Black Sampson; Blyškiuji ežiulių šaknys (pale coneflower root); Brauneria; Coneflower; Echinacea angustifolia, racine d' (narrow-leaved coneflower root); Echinacea pallida, racine d' (pale coneflower root); Echinacea purpurea, parties aériennes fleuries d' (purple coneflower herb); Echinacea purpurea, racine d' (purple coneflower root); Echinacea angustifoliae radix (narrow-leaved coneflower root); Echinacea pallidae radix (pale coneflower root); Echinacea purpureae herba (purple coneflower herb); Echinacea purpureae radix (purple coneflower root); Equinácea; Kaitapáivánhatunjuuri (narrow-leaved coneflower root); Kořen třapatky bledé (pale coneflower root); Kořen třapatky úzkolisté (narrow-leaved coneflower root); Läkerudbeckiarot (pale coneflower root); Liten läkerudbeckiarot (narrow-leaved coneflower root); Rohtopáivánhatunjuuri (pale coneflower root); Rudbeckia; Siauralapių ežiulių šaknys (narrow-leaved coneflower root); Sonnenhutkraut.

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

**Ph. Eur. 6.2** (Narrow-Leaved Coneflower Root; Echinaceae Angustifoliae Radix). The dried, whole, or cut underground parts of *Echinacea angustifolia*. It contains a minimum 0.5% of echinacoside ( $C_{35}H_{46}O_{20} = 786.7$ ), calculated with reference to the dried drug. Store uncommunitated. Protect from light.

**Ph. Eur. 6.2** (Pale Coneflower Root; Echinaceae Pallidae Radix). The dried, whole, or cut underground parts of *Echinacea pallida*. It contains a minimum 0.2% of echinacoside calculated with reference to the dried drug. Store uncommunitated. Protect from light.

**Ph. Eur. 6.2** (Purple Coneflower Herb; Echinaceae Purpureae Herba). The dried, whole or cut flowering aerial parts of *Echinacea purpurea*. It contains a minimum of 0.1% of the sum of caticaric acid ( $C_{13}H_{12}O_9 = 312.2$ ) and cichoric acid ( $C_{22}H_{18}O_{12} = 474.4$ ). Store uncommunitated.

**Ph. Eur. 6.2** (Purple Coneflower Root; Echinaceae Purpureae Radix). The dried, whole or cut underground parts of *Echinacea purpurea*. It contains a minimum of 0.5% of the sum of caticaric acid ( $C_{13}H_{12}O_9 = 312.2$ ) and cichoric acid ( $C_{22}H_{18}O_{12} = 474.4$ ). Store uncommunitated.

**USP 31** (Echinacea Angustifolia). It consists of the dried rhizome and roots of *Echinacea angustifolia* (Asteraceae), harvested in the autumn after 1 or more years of growth. It contains not less than 0.5% of total phenols. Protect from light.

**USP 31** (Echinacea Pallida). It consists of the dried rhizome and roots of *Echinacea pallida* (Asteraceae), harvested in the autumn after 3 or more years of growth. It contains not less than 0.5% of total phenols. Protect from light.

**USP 31** (Echinacea Purpurea Aerial Parts). The aerial parts of *Echinacea purpurea* (Asteraceae) harvested during the flowering stage. It contains not less than 1.0% of cichoric acid, and not less than 0.01% of decodecetraenoic acid isobutylamides ( $C_{18}H_{25}NO$ ), calculated on the dried basis. Store in airtight containers. Protect from light.

### Profile

Echinacea, the dried, whole, or cut underground parts of *Echinacea angustifolia* (*Brauneria angustifolia*), *E. pallida* (*B. pallida*), or *E. purpurea*, or the aerial parts of *E. purpurea*, is reported to have immunostimulant properties. It is used in herbal preparations for the prophylaxis of bacterial and viral infections.

**Homoeopathy.** Echinacea has been used in homoeopathic medicines under the following names: Echinacea purpurea; Echinacea purpurea ex planta tota; Echinacea purpurea, Planta tota; Echinacea angustifolia; Echin. an.

**Adverse effects.** The most common adverse effects reported on short-term use of echinacea were gastrointestinal and skin-related; these were generally transient and reversible.<sup>1</sup> Hypersensitivity reactions including anaphylaxis have been reported.<sup>1,4</sup>

- Huntley AL, *et al.* The safety of herbal medicinal products derived from Echinacea species. *Drug Safety* 2005; **28**: 387–400.
- Mullins RJ, Heddle R. Adverse reactions associated with echinacea: the Australian experience. *Ann Allergy Asthma Immunol* 2002; **88**: 42–51.
- Health Canada. Natural health products and adverse reactions. *Can Adverse React News* 2004; **14** (1); 2. Also available at: [http://www.hc-sc.gc.ca/dhp-mps/alt\\_formats/hpfb-dgpsa/pdf/medeff/carn-bcei\\_v14n1\\_e.pdf](http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/medeff/carn-bcei_v14n1_e.pdf) (accessed 11/08/05)
- Adverse Drug Reactions Advisory Committee (ADRAC). Adverse reactions to complementary medicines. *Aust Adverse Drug React Bull* 2005; **24**: 2. Also available at: <http://www.tga.health.gov.au/adr/aadr/aadr0502.htm> (accessed 11/08/05)

**Pharmacokinetics.** The pharmacokinetics of alkalimides extracted from *Echinacea angustifolia* roots have been studied<sup>1</sup> in human subjects. Fast absorption of some alkalimides was shown after oral use; highly lipophilic alkalimides could not be detected in plasma.

- Woelk K, *et al.* Bioavailability and pharmacokinetics of alkalimides from the roots of *Echinacea angustifolia* in humans. *J Clin Pharmacol* 2005; **45**: 683–9.

**Use in respiratory disorders.** Echinacea is widely used in herbal preparations to treat upper respiratory-tract infections such as the common cold. Studies<sup>1–3</sup> have produced conflicting results, but systematic reviews suggest that most have methodological flaws<sup>4</sup> rendering evidence of efficacy unconvincing.<sup>4,5</sup> A meta-analysis<sup>6</sup> of 14 randomised controlled studies suggested that echinacea does have a benefit in decreasing the incidence and duration of the common cold, although it was acknowledged that larger prospective studies controlling for several variables (e.g. species) are needed before it can be routinely recommended. Comparative evaluation of specific preparations is also difficult because of varying composition. Evaluation of the effect of 3 extracts of *Echinacea angustifolia* root, each produced by a different extraction method and with defined phytochemical profiles, demonstrated no clinically significant effects by any of them on experimental rhinovirus infection or ensuing illness compared with placebo.<sup>7</sup> Alkalimides, polysaccharides, and caffeic acid derivatives, which have been proposed as the active components of echinacea preparations, were present in varying amounts in the extracts.

- Turner RB, *et al.* Ineffectiveness of echinacea for prevention of experimental rhinovirus colds. *Antimicrob Agents Chemother* 2000; **44**: 1708–9.
- Barrett BP, *et al.* Treatment of the common cold with unrefined echinacea: a randomized, double-blind, placebo-controlled trial. *Ann Intern Med* 2002; **137**: 939–46.
- Taylor JA, *et al.* Efficacy and safety of echinacea in treating upper respiratory tract infections in children: a randomized controlled trial. *JAMA* 2003; **290**: 2824–30.
- Caruso TJ, Gwaltney JM. Treatment of the common cold with echinacea. *Clin Infect Dis* 2005; **40**: 807–10.
- Linde K, *et al.* Echinacea for preventing and treating the common cold. Available in The Cochrane Database of Systematic Reviews; Issue 1. Chichester: John Wiley; 2006 (accessed 31/07/08).
- Shah SA, *et al.* Evaluation of echinacea for the prevention and treatment of the common cold: a meta-analysis. *Lancet Infect Dis* 2007; **7**: 473–80.
- Turner RB, *et al.* An evaluation of *Echinacea angustifolia* in experimental rhinovirus infections. *N Engl J Med* 2005; **353**: 341–8.

### Preparations

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

**Austral.:** Echinacin; **Austria:** Echinacin; Echinacefor; Sarvita Immun; **Belg.:** Echinacin; **Braz.:** Enax; Equinacea†; Immunol; Immunocel†; Immunogreen; **Canada.:** Citranacea†; Triple Blend Echinacea; **Cz.:** Echinacin; **Immunaol.:** **Ger.:** aar vir; Cefatoc†; Echan; Echi†; Echiherb†; Echinacin; Echinacefor; Echinapur; Echinatur; Episorit; Esberitox mono; Lymphozit; Pasctoc forte-Injektopast†; Pasctocot mono†; Pasctocot Purpurea; Resistan mono; Resplant†; toxi-loges; Wriedimmun†; **Gr.:** Echinacin; **Hung.:** Echinacin; **Ital.:** EulMunit; **Mex.:** Immune Booster†; Regipax; **Pol.:** Echinapur; Echinerba; Immunol; Lymphozit; Purex; **Rus.:** Immunal (Иммунал); Immunorm (Иммунорм); **Spain:** Echinacin; Ekjan; Revitonil; **Switz.:** Echinacin; Echinacefor; Echinamed; Echiplant†; **UK:** Benylin Active Response†; Echinacea; Echinacefor; Phytocold; Skin Clear; **Venez.:** Flucaps.

**Multi-ingredient:** **Arg.:** Parodontax Fluor; SX-22; **Austral.:** Andrographis Complex; Andrographis Compound; Astragalus Complex; Broncalect; Cats Claw Complex; Cold and Flu Relief†; Cough Relief†; Diaco; Digest; Echinacea 4000; Echinacea ACE + Zinc; Echinacea Complex; Echinacea Lozenges; Euphrasia Complex; Flavos; Galium Complex†; Gartech; Herbal Cleanse†; Herbal Cold & Flu Relief†; Lifestem Herbal Plus Formula 8 Echinacea†; Logicin Natural Lozenges†; Odourless Garlic†; Proyeast†; Sambucus Complex†; Urganin†; Urinast†; **Austria:** Esberitox; Parodontax; Spasmo-Urganin; Urganin; **Belg.:** Medica Junior; Urganin; **Braz.:** Infantoss†; Malvaticin Natural; Malvaticin Natural Organic; Malvaticin Natural Soft; Parodontax; **Canada.:** Bentasil Licorice with Echinacea†; Benylin First Defense†; Echinacea Goldenseal Formula†; **Chile:** Citro-C; Paltomiel Plus; **Ger.:** Ermsch†; Esberitox N; Hevenephron duo†; **Hong Kong:** Urganin; **Indon.:** Biofos; Curmunos; Ekinaise; Flaviv; Hepasil; Hepatin; Imboost; Imboost Force; Imudator; Norflam; Primunox; Proimbus; Proza; Staminio; StarMuno; Stimox; Tribost; **Israel:** Parodontax†; Urganin; **Ital.:** Bodyguard; Dermilia Flebozin; Golatus; Immunit Plus; Immunit†; Immun-up; Influzinc; Nepiros; Probiog; Promix 3†; Promix†; Ribovir; Scleroviv H; **Malaysia:** Echinacea Plus†; Esberitox N; Total Mant†; **Mex.:** Gripealeta†; **NZ:** Lice Blast-er; Strepsils Echinacea Defence; **Pol.:** Cardiobonisol; Echinast; Esberitox N; Immunofort; Pectobonisol; Plantifort; Reumaherb; **Port.:** Neo Urganin; Spasmo-Urganin†; Vitace; **Rus.:** Prostanorm (Простанорм); **S.Afr.:** Spasmo-Urganin†; **Venez.:** **Singapore:** Noricaven†; Proza; **Spain:** Neo Ur-