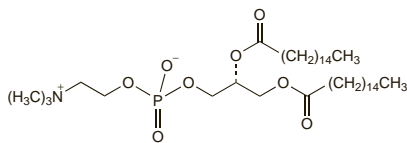


**Colfosceril Palmitate** (BAN, USAN, rINN)

Colfosceril, Palmitate de; Colfosceril Palmitas; Dipalmitoylphosphatidylcholine; DPPC; Palmitato de colfoscerilo; 129Y83. 1,2-Dipalmitoyl-sn-glycero(3)phosphocholine.

Колфосцерил Пальмитат  
C<sub>40</sub>H<sub>80</sub>NO<sub>8</sub>P = 734.0.  
CAS — 63-89-8.  
ATC — R07AA01.  
ATC Vet — QR07AA01.



**Description.** Colfosceril palmitate is a phospholipid which forms an important constituent of natural and many synthetic pulmonary surfactant compounds.

**Lucinactant** (USAN)

ATI-02; KL<sub>4</sub>-surfactant.

**Description.** Lucinactant is a mixture of sinapultide, colfosceril palmitate, sodium palmitoyloleoylphosphatidyl glycerol, and palmitic acid.

**Poractant Alfa** (BAN)

CAS — 129069-19-8.

**Description.** Poractant alfa is an extract of porcine lung containing not less than 90% of phospholipids, about 1% of hydrophobic proteins (SP-B and SP-C), and about 9% of other lipids.

**Pumactant** (BAN)

Artificial Lung Expanding Compound.

**Description.** Pumactant is a mixture of colfosceril palmitate and phosphatidyl glycerol (2-oleoyl-1-palmitoyl-sn-glycero(3)phospho(1)-sn-glycerol) in the proportion 7:3.

**Sinapultide** (USAN, rINN)

ATI-01; Sinapultida; Sinapultidum.

Синапультид  
CAS — 138531-07-4.

**Description.** Sinapultide is a synthetic peptide that mimics the actions of human surfactant protein B, an important constituent of natural pulmonary surfactant compounds.

**Adverse Effects and Precautions**

Surfactant therapy may be associated with an increased risk of pulmonary haemorrhage, especially in more premature infants. Therapy should only be given where there are adequate facilities for ventilation and monitoring. Rapid chest expansion and improvement of oxygenation may follow successful treatment, and peak ventilatory pressure and inspired oxygen concentration may need to be reduced promptly to avoid the risk of pneumothorax and hyperoxaemia. A transient decrease in brain electrical activity has been reported in neonates given surfactant but its significance is unknown. Transient bradycardia has also been reported. Giving surfactant has occasionally been associated with obstruction of the endotracheal tube by mucus.

While surfactant therapy is clearly associated with an increased risk of pulmonary haemorrhage,<sup>1-4</sup> meta-analysis suggests that the risk is small compared with the benefits.<sup>1</sup> However, neonates who do develop moderate or severe pulmonary haemorrhage after surfactant therapy are at increased risk of death or short-term morbidity.<sup>5</sup> Haemodynamic changes associated with surfactant therapy or consequent pulmonary haemorrhage may also predispose premature infants to intracranial (periventricular) haemorrhage.<sup>3,6</sup> Early preventive use of surfactant in very low birth-weight infants may be associated with a poorer neurodevelopmental outcome,<sup>7</sup> although a long-term follow-up study<sup>8</sup> of premature infants born in the surfactant era concluded that these children had similar neurodevelopmental outcomes to such children born before the introduction of surfactant therapy. Decreased brain electrical activity has been reported after surfactant treatment.<sup>9</sup>

The rate of instillation of surfactant may be significant: one study,<sup>10</sup> in which the apparatus was adapted so that mechanical ventilation could continue while giving surfactant, found that rapid instillation over a 5-minute period provoked a transient increase in cerebral blood flow velocity associated with an increase in carbon dioxide tension, compared with slow instillation over 15 minutes. Although the authors acknowledged that such changes were likely to be related to several factors, particularly the type of surfactant, they recommended that, until further data were available, instillation should take place slowly, over at least 15 to 20 minutes.

1. Raju TNK, Langenberg P. Pulmonary hemorrhage and exogenous surfactant therapy: a metaanalysis. *J Pediatr* 1993; **123**: 603-10.

- Majeed-Saidan MA, et al. Pulmonary haemorrhage in low-birthweight babies. *Lancet* 1993; **341**: 120.
- Rogers D. Pulmonary haemorrhage, surfactant, and low-birth-weight babies. *Lancet* 1993; **341**: 698.
- Pappin A, et al. Extensive intraalveolar pulmonary hemorrhage in infants dying after surfactant therapy. *J Pediatr* 1994; **124**: 621-6.
- Pandit PB, et al. Outcome following pulmonary haemorrhage in very low birthweight neonates treated with surfactant. *Arch Dis Child Fetal Neonatal Ed* 1999; **81**: F40-F44.
- Gunkel JH, Banks PLC. Surfactant therapy and intracranial hemorrhage: review of the literature and results of new analyses. *Pediatrics* 1993; **92**: 775-86.
- Vaucher YE, et al. Outcome at twelve months of adjusted age in very low birthweight infants with lung immaturity: a randomized placebo-controlled trial of human surfactant. *J Pediatr* 1993; **122**: 126-32.
- D'Angio CT, et al. Longitudinal, 15-year follow-up of children born at less than 29 weeks' gestation after introduction of surfactant therapy into a region: neurologic, cognitive, and educational outcomes. *Pediatrics* 2002; **110**: 1094-1102.
- Hellström-Westas L, et al. Cerebroelectrical depression following surfactant treatment in preterm neonates. *Pediatrics* 1992; **89**: 643-7.
- Saliba E, et al. Instillation rate effects of Exosurf on cerebral and cardiovascular haemodynamics in preterm neonates. *Arch Dis Child* 1994; **71**: F174-8.

**Uses and Administration**

Pulmonary surfactants are compounds with surface active properties similar to those natural substances in the lung that help to maintain the patency of the airways by reducing the surface tension of pulmonary fluids. Exogenous pulmonary surfactants are used in the treatment of neonatal respiratory distress syndrome (p.1508) in premature infants, and may also be given for prevention in infants considered to be at risk of developing the syndrome. Doses vary, but most pulmonary surfactants are given in recommended doses of 100 to 200 mg phospholipids per kg birth-weight; a suggested dose for colfosceril palmitate is 67.5 mg/kg. For the treatment of overt neonatal respiratory distress syndrome, the initial dose is given as soon as possible after diagnosis, while for prevention it is given as soon as possible after birth. It is given as a suspension via an endotracheal tube to intubated neonates receiving mechanical ventilation. Manufacturers may recommend regimens with or without disconnection from the ventilator. Repeat doses may be given if necessary, although the number of doses and the dosage interval varies.

Pulmonary surfactants have also been tried in bronchopulmonary dysplasia in premature infants, meconium aspiration syndrome in newborn infants, and acute respiratory distress syndrome in adults. A similar compound lusapultide is also under investigation for aspiration pneumonitis.

**Acute respiratory distress syndrome.** Pulmonary surfactants have been investigated for acute respiratory distress syndrome (p.1498). In adults, they have been given by intrabronchial instillation<sup>1</sup> or nebulisation<sup>2-4</sup> but results have been largely disappointing. Sequential bronchopulmonary segmental lavage with a synthetic surfactant has also been tried<sup>5</sup> and appeared to be well tolerated. Endotracheal poractant alfa moderately improved oxygenation in some children with severe acute respiratory distress syndrome secondary to pulmonary or systemic disease.<sup>6</sup>

- Haslam PL, et al. Surfactant replacement therapy in late-stage adult respiratory distress syndrome. *Lancet* 1994; **343**: 1009-11.
- do Campo JL, et al. Natural surfactant aerosolisation in adult respiratory distress syndrome. *Lancet* 1994; **344**: 413-14.
- Weg JG, et al. Safety and potential efficacy of an aerosolized surfactant in human sepsis-induced adult respiratory distress syndrome. *JAMA* 1994; **272**: 1433-8.
- Anzueto A, et al. Aerosolized surfactant in adults with sepsis-induced respiratory distress syndrome. *N Engl J Med* 1996; **334**: 1417-21.
- Wiswell TE, et al. Bronchopulmonary segmental lavage with Surfaxin (KL-Surfactant) for acute respiratory distress syndrome. *Am J Respir Crit Care Med* 1999; **160**: 1188-95.
- López-Herce J, et al. Surfactant treatment for acute respiratory distress syndrome. *Arch Dis Child* 1999; **80**: 248-52.

**Drowning.** Reference to the use of colfosceril palmitate in the management of a 9-year-old rescued after near drowning.<sup>1</sup>

- McBrien M, et al. Artificial surfactant in the treatment of near drowning. *Lancet* 1993; **342**: 1485-6.

**Meconium aspiration syndrome.** Meconium aspiration syndrome produces respiratory distress in infants born at term or later and is a consequence of disturbances of the pulmonary surfactant system. Bolus doses of exogenous pulmonary surfactant are of benefit in some ventilated infants, although lung lavage with dilute surfactant is also under investigation.<sup>1</sup> Results from a pilot study<sup>2</sup> of beractant as a tracheobronchial lavage fluid for the treatment of infants with severe meconium aspiration syndrome were promising, and a small comparative trial<sup>3</sup> found that bronchoalveolar lavage with diluted beractant, with or without intravenous dexamethasone, significantly improved oxygenation in neonates when compared with standard therapy. Systematic review<sup>4</sup> of 4 randomised controlled trials evaluating the effect of pulmonary surfactants also found encouraging results, although comparison with other established treatments for meconium aspiration syndrome remains to be done.

- Dargaville PA, Mills JF. Surfactant therapy for meconium aspiration syndrome: current status. *Drugs* 2005; **65**: 2569-91.
- Lam BCC, Yeung CY. Surfactant lavage for meconium aspiration syndrome: a pilot study. *Pediatrics* 1999; **103**: 1014-18.

- Salvia-Roigés MD, et al. Efficacy of three treatment schedules in severe meconium aspiration syndrome. *Acta Paediatr* 2004; **93**: 60-5.
- El Shahed AI, et al. Surfactant for meconium aspiration syndrome in full term/near term infants. Available in The Cochrane Database of Systematic Reviews; Issue 3. Chichester: John Wiley; 2007 (accessed 13/06/08).

**Preparations**

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

**Arg.:** Baby Fact B; Exosurf; Natsurf; Surfactante B; Survant; **Austral.:** Curosurf; Exosurf; Survant; **Austria:** Alveofact; Curosurf; Exosurf; Survant; **Belg.:** Alveofact; Curosurf; Survant; **Braz.:** Alveofact; Curosurf; Exosurf; Survant; **Canada:** BLES; Exosurf; Survant; **Chile:** Exosurf; Survant; **Cz.:** Alveofact; Curosurf; Exosurf; Survant; **Denm.:** Curosurf; Exosurf; Survant; **Fin.:** Curosurf; **Fr.:** Curosurf; Survant; **Ger.:** Alveofact; Curosurf; Survant; **Gr.:** Alveofact; Curosurf; Exosurf; Survant; **Hong Kong:** Curosurf; Exosurf; Survant; **Hung.:** Curosurf; Survant; **Indon.:** Survant; **Irl.:** Curosurf; Exosurf; **Israel:** Curosurf; Exosurf; **Infusur:** **Ital.:** Curosurf; Exosurf; **Jpn:** Surf-actin; **Malaysia:** Survant; **Mex.:** Exosurf; Survant; **Neth.:** Alveofact; Curosurf; Exosurf; **Norw.:** Curosurf; Survant; **NZ:** Curosurf; Survant; **Philipp.:** Survant; **Pol.:** Alveofact; Curosurf; Survant; **Port.:** Curosurf; **Rus.:** Curosurf (Kypocypb); **S.Afr.:** Curosurf; Survant; **Singapore:** **Spain:** Curosurf; Survant; **Swed.:** Curosurf; Survant; **Switz.:** Curosurf; Survant; **Thai:** Curosurf; Survant; **UK:** Curosurf; Survant; **USA:** Curosurf; Exosurf; Infusur; Survant; **Venez.:** Survant.

**Pulsatilla**

Anémone pulsatile; Meadow Anemone; Pasque Flower;  
CAS — 62887-80-3.

**Profile**

Pulsatilla is the whole flowering plant of *Pulsatilla vulgaris* (*Anemone pulsatilla*) or *Pulsatilla pratensis* (Ranunculaceae). It has been used in herbal preparations for the treatment of conditions including nervous disorders, circulatory disorders, and gynaecological disorders and benign prostatic hyperplasia.

**Homeopathy.** Pulsatilla has been used in homeopathic medicines under the following names: Pulsatilla pratensis; Pulsatilla vulgaris; Pulsatilla nigricans; Puls.

**Preparations**

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

**USA:** Yeast-X†.

**Multi-ingredient:** **Austral.:** Bioglan Cirlfo; Calmo; Lifesystem Herbal Formula 4 Women's Formula†; Proflor; Women's Formula Herbal Formula 3†; **Braz.:** Eviprost†; **Cz.:** Cicaderma; **Fr.:** Cicaderma; Hepatoum; Histofluine P; **Ger.:** Eviprost N; **Indon.:** Eviprost; **Jpn:** Eviprost; **Port.:** Cicaderma; **S.Afr.:** Cough Elixir; **Singapore:** Eviprost; **UK:** Anased; Menopause Relief; Period Pain Relief; Prementaid.

**Pumilio Pine Oil**

Dwarf Pine Needle Oil; Dwarf Pine Oil; Essence de Pin de Montagne; Latschenöl; Oleum Pini Pumilionis; Olio di Mugjo; Pin de montagne, huile essentielle de; Pini pumilionis aetheroleum; Pino mugjo, aceite esencial de.  
CAS — 8016-46-4.

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

**Ph. Eur. 6.2** (Dwarf Pine Oil). An essential oil obtained by steam distillation of the fresh leaves and twigs of *Pinus mugjo*. A suitable antioxidant may be added. Relative density 0.857 to 0.868. A clear, colourless or pale yellow liquid. Store in inert, well-filled, airtight containers at a temperature not exceeding 25°. Protect from light.

**Profile**

Pumilio pine oil is a volatile oil obtained by distillation from the fresh leaves of *Pinus mugjo* var. *pumilio* (Pinaceae). It has been inhaled with steam, sometimes with other essential oils, to relieve cough and nasal congestion and has been applied externally as a rubefacient. It has also been used as a perfume.

*P. mugjo* is a source of pine needle oil (see Pine Oil, p.2368).

**Preparations**

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

**Multi-ingredient:** **Austral.:** Biosal Arthritis; Biosal†; Goanna Heat Cream; Goanna Salve; Karvol†; Menalotion†; Vicks Inhaler; **Austria:** Bergeist; Bronchostop; Colda; Emser Nasensalbe; Erkaltungsbalsam; Expectal-Balsam; Leukonka-Rheuma-Bad; Luof Balsam; Mentipin; Nasanal; Opino; Piniment; **Cz.:** Thrombocid; Transpulmin; **Ger.:** Aerosol Spitzner N†; Dolo-cyl Em-eukal†; Emser Nasensalbe N†; Euflex; Franzbranntwein; Hevertopex N†; Klosterfrau Franzbranntwein Latschenkiefel; Nasentropfen-ratiopharm†; Ner-fluid S; polio-elan; Rosarhron†; Thrombocid; **Gr.:** Opino-jel; **Irl.:** Karvol; **Israel:** Karvol; Mentholatum Balm; **Ital.:** Altuss; Antipulmina†; Broncosedina; Pinedrin†; Pumiene Vapo; **Malaysia:** Puro-porent†; **Neth.:** Luof Verkoudeheidsbalsem; **NZ:** Vicks Inhaler; **Port.:** Thrombocid; **Switz.:** Eau-de-vie de France avec huile de pin pain du Tirol†; Eucapinol; Liberol Baby N; Liberol Bain†; Liberol N; Makaphyt Baume†; Pinimenthol†; Piniol Pommade Speciale†; Thrombocid; **UK:** Allens Pine & Honey; Karvol; Mentholatum Rub; Original Cabdrivers Expectorant; Potter's Catarrh Pastilles.

**Punarnava**

Punarnaba.

**Profile**

Punarnava is the fresh or dried plant *Boerhaavia diffusa* (*B. repens*) (Nyctaginaceae), containing an alkaloid, punarnavine. It has been used as a diuretic and for liver disorders, usually in the form of a liquid extract.