

**Profile**

Pipazetate hydrochloride is a centrally acting cough suppressant that also has some peripheral actions in non-productive cough (p.1547). It has been given by mouth and rectally.

**Overdosage.** A healthy 4-year-old child became somnolent and agitated, with convulsions, followed by coma, after swallowing an unknown number of tablets containing pipazetate; cardiac arrhythmias also developed.<sup>1</sup> Fatal toxicity has also been reported in children.<sup>2,3</sup>

1. da Silva OA, Lopez M. Pipazetate—acute childhood poisoning. *Clin Toxicol* 1977; **11**: 455–8.
2. Bonavita V, et al. Accidental lethal pipazetate poisoning in a child. *Z Rechtsmed* 1982; **89**: 145–8.
3. Soto E, et al. Pipazetate lethality in a baby. *Vet Hum Toxicol* 1993; **35**: 41.

**Preparations**

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

**Braz.:** Selvigon; **Ital.:** Selvigon; **Mex.:** Selvigon; **Thai.:** Transpulmin†.

**Poppy Capsule**

Dormideiras; Fruit du Pavot; Fruto de adormidera; Mohnfrucht; Papaveris Capsula; Poppy Heads.

Маковая Коробочка

**Pharmacopoeias.** In *Chin.*

**Profile**

Poppy capsule consists of dried fruits of *Papaver somniferum* (Papaveraceae), collected before dehiscence has occurred, containing very small amounts of morphine with traces of other opium alkaloids. It is mildly sedative and has been used as a liquid extract or syrup in cough mixtures.

**Preparations**

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

**Multi-ingredient:** **Belg.:** Sedemol; Sulf-a-Sedemol; **Braz.:** Malvodon.

**Prenoxdiazine Hydrochloride** (rINN)

Hydrocloruro de prenoxidiazina; HK-256; Prenoxdiazin Hydrochloride; Prénoxidiazine, Chlorhydrate de; Prenoxdiazini Hydrochloridum. 3-(2,2-Diphenylethyl)-5-(2-piperidinoethyl)-1,2,4-oxadiazole hydrochloride.

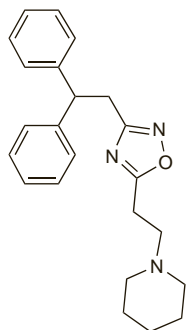
Преноксидиазина Гидрохлорид

$C_{23}H_{27}N_3O.HCl = 397.9$ .

CAS — 47543-65-7 (prenoxdiazine); 37671-82-2 (prenoxdiazine hibenzenate); 982-43-4 (prenoxdiazine hydrochloride).

ATC — R05DB18.

ATC Vet — QR05DB18.



(prenoxdiazine)

**Profile**

Prenoxdiazine hydrochloride is a peripherally acting cough suppressant for non-productive cough (p.1547) that has been given orally. Prenoxdiazine hibenzenate has also been used.

**Preparations**

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

**Cz.:** Libexin†; **Hung.:** Libexin; Rhinathiol Tusso; **India:** Libexin; **Rus.:** Libexin (Либексин).

**Multi-ingredient:** **Ital.:** Broncofluid; Libexin Mucolitico.

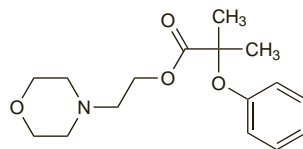
**Promolate** (rINN)

Morphethylbutyne; Promolato; Promolatum. 2-Morpholinoethyl 2-methyl-2-phenoxypropionate.

Промолат

$C_{16}H_{23}NO_4 = 293.4$ .

CAS — 3615-74-5.

**Profile**

Promolate is a cough suppressant that has been given rectally to infants.

**Preparations**

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

**Chile:** Atusil.

**Pseudoephedrine** (BAN, rINN)

d-Ψ-Ephedrine; d-Isoephedrine; Pseudoefedrin; Pseudoefedrin; Pseudoefedrina; Pseudoéphédrine; Pseudoephedrinum. (+)-(1S,2S)-2-Methylamino-1-phenylpropan-1-ol.

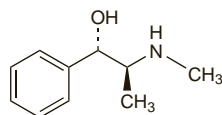
Псевдоэфедрин

$C_{10}H_{15}NO = 165.2$ .

CAS — 90-82-4.

ATC — R01BA02.

ATC Vet — QR01BA02.



**Description.** Pseudoephedrine is an alkaloid obtained from *Ephedra* spp.

**Pseudoephedrine Hydrochloride**

(BANM, USAN, rINN)

Hydrocloruro de pseudoefedrina; Pseudoefedrinhydrochlorid; Pseudoefedrin-hydrochlorid; Pseudoefedrinhydrochlorid; Pseudoefedrinhydrochloridas; Pseudoéphédrine, chlorhydrate de; Pseudoephedriini hydrochloridum; Psödoefedrin Hidroklorür; Psödoefedrin-hidroklorid.

Псевдоэфедрина Гидрохлорид

$C_{10}H_{15}NO.HCl = 201.7$ .

CAS — 345-78-8.

ATC — R01BA02.

ATC Vet — QR01BA02.

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

**Ph. Eur. 6.2** (Pseudoephedrine Hydrochloride). A white or almost white, crystalline powder or colourless crystals. Freely soluble in water and in alcohol; sparingly soluble in dichloromethane. Protect from light.

**USP 31** (Pseudoephedrine Hydrochloride). A fine, white to off-white crystalline powder, having a faint characteristic odour. Soluble 1 in 0.5 of water, 1 in 3.6 of alcohol, 1 in 91 of chloroform, and 1 in 7000 of ether. pH of a 5% solution in water is between 4.6 and 6.0. Store in airtight containers. Protect from light.

**Pseudoephedrine Sulfate** (USAN, rINN)

Pseudoéphédrine, Sulfate de; Pseudoephedrine Sulphate (BANM); Pseudoephedriini Sulfas; Sch-4855; Sulfato de pseudoefedrina.

Псевдоэфедрина Сульфат

$(C_{10}H_{15}NO)_2.H_2SO_4 = 428.5$ .

CAS — 7460-12-0.

ATC — R01BA02.

ATC Vet — QR01BA02.

**Pharmacopoeias.** In *US*.

**USP 31** (Pseudoephedrine Sulfate). Odourless, white crystals or crystalline powder. Freely soluble in alcohol. pH of a 5% solution in water is between 5.0 and 6.5. Store in airtight containers. Protect from light.

**Adverse Effects and Precautions**

As for Ephedrine, p.1558. The commonest adverse effects of pseudoephedrine include tachycardia, anxiety,

restlessness, and insomnia; skin rashes and urinary retention have occasionally occurred. Hallucinations have been reported rarely, particularly in children.

◊ In response to reports in the USA of overdoses associated with cough and cold medications, the CDC and the National Association of Medical Examiners investigated deaths in infants aged under 12 months associated with such use; 3 cases were identified. All 3 infants had high concentrations of pseudoephedrine in postmortem blood samples, 2 had detectable blood concentrations of dextromethorphan and paracetamol, and 1 was also found to have detectable concentrations of doxylamine. None of the deaths were determined to be intentional. Two infants had evidence of respiratory infection upon autopsy; no cardiac abnormalities were found in any of the infants.<sup>1</sup>

1. CDC. Infant deaths associated with cough and cold medications—two States, 2005. *MMWR* 2007; **56**: 1–4. Also available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5601a1.htm> (accessed 19/04/07)

**Abuse.** Acute psychosis and visual and tactile hallucinations have been reported<sup>1</sup> in an 18-year-old male after intravenous misuse of pseudoephedrine hydrochloride. Pseudoephedrine has also been used for the illicit manufacture of street stimulants such as metamfetamine (p.2158).

For reference to toxic effects after long-term use of over-the-counter preparations containing sympathomimetics, such as pseudoephedrine, see under Ephedrine, p.1558.

1. Sullivan G. Acute psychosis following intravenous abuse of pseudoephedrine: a case report. *J Psychopharmacol* 1996; **10**: 324–5.

**Breast feeding.** The American Academy of Pediatrics<sup>1</sup> states that, although usually compatible with breast feeding, preparations used by breast-feeding mothers that contain pseudoephedrine with dexbrompheniramine maleate have resulted in crying, irritability, and poor sleep patterns in the infant.

The concentrations of pseudoephedrine and triprolidine in plasma and breast milk of 3 mothers for up to 48 hours after ingestion of a preparation containing pseudoephedrine hydrochloride 60 mg with triprolidine hydrochloride 2.5 mg have been studied.<sup>2</sup> Concentrations of pseudoephedrine in milk were consistently higher than in plasma; the half-life in both fluids was between 4.2 and 7.0 hours. Assuming a generous milk secretion of 500 mL over 12 hours it was calculated that the excreted dose was the equivalent of 250 to 330 micrograms of pseudoephedrine base, or 0.5 to 0.7% of the dose ingested by the mothers. Triprolidine did not appear to be concentrated in breast milk. The amounts of pseudoephedrine and triprolidine distributed into breast milk were probably not high enough to warrant cessation of breast feeding.

A small, randomised, crossover study concluded that a single dose of 60 mg pseudoephedrine hydrochloride decreased 24-hour milk production by 24%. The authors of the study suggested that pseudoephedrine might be of benefit for suppressing excess milk production.<sup>3</sup>

1. American Academy of Pediatrics. The transfer of drugs and other chemicals into human milk. *Pediatrics* 2001; **108**: 776–89. Correction. *ibid.*: 1029. Also available at: <http://aappolicy.aappublications.org/cgi/content/full/pediatrics%3b108/3/776> (accessed 05/01/07)
2. Findlay JWA, et al. Pseudoephedrine and triprolidine in plasma and breast milk of nursing mothers. *Br J Clin Pharmacol* 1984; **18**: 901–6.
3. Aljazzaf K, et al. Pseudoephedrine: effects on milk production in women and estimation of infant exposure via breastmilk. *Br J Clin Pharmacol* 2003; **56**: 18–24.

**Convulsions.** A child who suffered a generalised seizure after ingesting a large quantity of pseudoephedrine hydrochloride tablets was believed to be the first report of convulsions associated with overdose of a preparation containing the drug as a single ingredient.<sup>1</sup>

1. Clark RF, Curry SC. Pseudoephedrine dangers. *Pediatrics* 1990; **85**: 389–90.

**Effects on the gastrointestinal tract.** Ischaemic colitis has been reported<sup>1,3</sup> after acute or chronic use of pseudoephedrine in combination cold and allergy preparations. In one case<sup>3</sup> the authors suggested that use with tramadol may have contributed to adrenergic vasoconstriction by inhibition of noradrenaline re-uptake.

1. Dowd J, et al. Ischemic colitis associated with pseudoephedrine: four cases. *Am J Gastroenterol* 1999; **94**: 2430–4.
2. Lichtenstein GR, Yee NS. Ischemic colitis associated with decongestant use. *Ann Intern Med* 2000; **132**: 682.
3. Traino AA, et al. Probable ischemic colitis caused by pseudoephedrine with tramadol as a possible contributing factor. *Ann Pharmacother* 2004; **38**: 2068–70.

**Effects on mental function.** Adverse mental effects (particularly in children) have been associated with combination preparations containing pseudoephedrine.<sup>1–5</sup> See also Abuse, above.

1. Leighton KM. Paranoid psychosis after abuse of Actifed. *BMJ* 1982; **284**: 789–90.
2. Sankey RJ, et al. Visual hallucinations in children receiving decongestants. *BMJ* 1984; **288**: 1369.
3. Stokes MA. Visual hallucinations in children receiving decongestants. *BMJ* 1984; **288**: 1540.

4. Roberge RJ, *et al.* Dextromethorphan and pseudoephedrine-induced agitated psychosis and ataxia: case report. *J Emerg Med* 1999; **17**: 285–8.
5. Soutullo CA, *et al.* Psychosis associated with pseudoephedrine and dextromethorphan. *J Am Acad Child Adolesc Psychiatry* 1999; **38**: 1471–2.

**Effects on the skin.** Recurrent pseudo-scarlatina has been described in a female patient and attributed, on some occasions at least, to ingestion of pseudoephedrine.<sup>1</sup> Further fixed drug eruptions associated with pseudoephedrine have been reported.<sup>2,4</sup> In another woman, an erythematous macular rash developed 5/ hours after an oral challenge with pseudoephedrine 60 mg; other symptoms, which mimicked the effects of toxic shock syndrome, included nausea and vomiting, fever, orthostatic hypotension, light-headedness, fatigue, and desquamation of the skin on her palms and soles.<sup>3</sup> However, considering the frequent use of pseudoephedrine in over-the-counter medications, associated drug eruptions generally appear to be rare.<sup>2</sup>

1. Taylor BJ, Duffill MB. *Br J Dermatol* 1988; **118**: 827–9.
2. Camisa C. Fixed drug reactions to pseudoephedrine hydrochloride. *Br J Dermatol* 1989; **120**: 857–8.
3. Cavanah DK, Ballas ZK. Pseudoephedrine reaction presenting as recurrent toxic shock syndrome. *Ann Intern Med* 1993; **119**: 302–3.
4. Hauken M. Fixed drug eruption and pseudoephedrine. *Ann Intern Med* 1994; **120**: 442.

**Pregnancy.** During pregnancy taking pseudoephedrine with paracetamol has been suggested to increase the risk of gastro-schisis (defective closure of the abdominal wall) in newborns.<sup>1</sup> Although the evidence for this is weak, it is advisable that pseudoephedrine should be avoided during pregnancy because of the severity of the abnormality and the availability of alternatives to pseudoephedrine.

1. Werler MM, *et al.* Maternal medication use and risks of gastro-schisis and small intestinal atresia. *Am J Epidemiol* 2002; **155**: 26–31.

**Tolerance.** In 34 healthy males given pseudoephedrine 120 or 150 mg twice daily for 7 days, as a modified-release preparation, mean plasma concentrations were about 450 or 510 nanograms/mL, respectively. Adverse effects (dry mouth, anorexia, insomnia, anxiety, tension, restlessness, tachycardia, palpitations) were common; there was some evidence of tachyphylaxis.<sup>1</sup>

1. Dickerson J, *et al.* Dose tolerance and pharmacokinetic studies of L(+) pseudoephedrine capsules in man. *Eur J Clin Pharmacol* 1978; **14**: 253–9.

## Interactions

As for Ephedrine, p.1559. Pseudoephedrine may cause a hypertensive crisis in patients receiving a MAOI (including a RIMA). For additional warnings see under phenelzine (p.418) and moclobemide (p.411). For mention of a possible interaction between pseudoephedrine and tramadol, see Effects on the Gastrointestinal Tract, above.

**Antacids.** The absorption rate of pseudoephedrine hydrochloride was increased by aluminium hydroxide mixture but was decreased by kaolin; in the latter case adsorption may have competed with absorption.<sup>1</sup>

1. Lucarotti RL, *et al.* Enhanced pseudoephedrine absorption by concurrent administration of aluminium hydroxide gel in humans. *J Pharm Sci* 1972; **61**: 903–5.

**Vaccines.** A 21-year-old mildly obese man taking pseudoephedrine in an over-the-counter formulation for weight loss collapsed and died with a core temperature of 42.2° while exercising, shortly after inoculation with Japanese encephalitis vaccine and typhoid vaccine.<sup>1</sup> The combined effects of the pseudoephedrine, activity, and the pyrogenic action of the vaccines appeared to have contributed to failure of the thermoregulatory system.

1. Franklin QJ. Sudden death after typhoid and Japanese encephalitis vaccination in a young male taking pseudoephedrine. *Mil Med* 1999; **164**: 157–9.

## Pharmacokinetics

Pseudoephedrine is readily absorbed from the gastrointestinal tract. It is excreted largely unchanged in the urine with small amounts of its hepatic metabolite. It has a half-life of about 5 to 8 hours; elimination is enhanced and half-life accordingly shorter in acid urine. Small amounts are distributed into breast milk.

### References

1. Simons FER, *et al.* Pharmacokinetics of the orally administered decongestants pseudoephedrine and phenylpropanolamine in children. *J Pediatr* 1996; **129**: 729–34.
2. Chester N, *et al.* Elimination of ephedrine in urine following multiple dosing: the consequences for athletes, in relation to doping control. *Br J Clin Pharmacol* 2004; **57**: 62–7.

## Uses and Administration

Pseudoephedrine is a direct- and indirect-acting sympathomimetic (p.1408). It is a stereoisomer of ephedrine (p.1558) and has a similar action, but has been

stated to have less pressor activity and fewer CNS effects.

Pseudoephedrine and its salts are given orally for the symptomatic relief of nasal congestion (p.1548). They are commonly combined with other ingredients in preparations intended for the relief of cough and cold symptoms.

Pseudoephedrine hydrochloride or sulfate are generally given orally in doses of 60 mg every 4 to 6 hours up to a maximum of 4 doses in 24 hours. For children's doses, see Administration in Children, below. Modified-release preparations are also available; a usual adult dose is 120 mg every 12 hours or 240 mg every 24 hours.

Other uses of pseudoephedrine include the control of urinary incontinence (p.2180) in some patients. It has also been given in the management of some forms of priapism (see under Metaraminol, p.1333).

Pseudoephedrine polistirex (a pseudoephedrine and sulfonated diethenylbenzene-ethenylbenzene copolymer complex) has also been used, as has pseudoephedrine tannate.

**Administration in children.** The BNFC states there is little evidence to support the use of systemic decongestants in children. However, the following oral doses of pseudoephedrine hydrochloride are suggested for children in the management of mucosal congestion of the upper respiratory tract:

- 2 to 6 years: 15 mg 3 or 4 times daily
- 6 to 12 years: 30 mg 3 or 4 times daily

Over-the-counter cough and cold preparations containing sympathomimetic decongestants (including pseudoephedrine) should be used with caution in children and generally avoided in those under 2 years of age (see p.1547).

**Barotrauma.** Results from a controlled study<sup>1</sup> suggest that pseudoephedrine given to adults at least 30 minutes before flying appears to decrease the incidence of ear pain associated with pressure changes.<sup>1</sup> However, a similar decrease in risk was not noted in children.<sup>2</sup>

1. Jones JS, *et al.* A double-blind comparison between oral pseudoephedrine and topical oxymetazoline in the prevention of barotrauma during air travel. *Am J Emerg Med* 1998; **16**: 262–4.
2. Buchanan BJ, *et al.* Pseudoephedrine and air travel-associated ear pain in children. *Arch Pediatr Adolesc Med* 1999; **153**: 466–8.

## Preparations

**BP 2008:** Pseudoephedrine Tablets;

**USP 31:** Acetaminophen and Pseudoephedrine Hydrochloride Tablets; Acetaminophen, Dextromethorphan Hydrobromide, Doxylamine Succinate, and Pseudoephedrine Hydrochloride Oral Solution; Acetaminophen, Diphenhydramine Hydrochloride, and Pseudoephedrine Hydrochloride Tablets; Chlorpheniramine Maleate and Pseudoephedrine Hydrochloride Extended-release Capsules; Chlorpheniramine Maleate and Pseudoephedrine Hydrochloride Oral Solution; Dextrobrompheniramine Maleate and Pseudoephedrine Sulfate Oral Solution; Diphenhydramine and Pseudoephedrine Capsules; Fexofenadine Hydrochloride and Pseudoephedrine Hydrochloride Extended-Release Tablets; Guaifenesin and Pseudoephedrine Hydrochloride Capsules; Guaifenesin, Pseudoephedrine Hydrochloride, and Dextromethorphan Hydrobromide Capsules; Ibuprofen and Pseudoephedrine Hydrochloride Tablets; Pseudoephedrine Hydrochloride Extended-Release Capsules; Pseudoephedrine Hydrochloride Extended-release Tablets; Pseudoephedrine Hydrochloride Syrup; Pseudoephedrine Hydrochloride Tablets; Pseudoephedrine Hydrochloride, Carbinoxamine Maleate, and Dextromethorphan Hydrobromide Oral Solution; Triprolidine and Pseudoephedrine Hydrochlorides Syrup; Triprolidine and Pseudoephedrine Hydrochlorides Tablets.

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

**Arg.:** Aseptobron Descongestivo; Mex; Qura Plus; **Austral.:** Chemists Own Sinus Relief; Demazin Sinus; Dimetapp Sinus; Logicin Sinus; Nyal Plus+ Decongestant; Sudafed; Sudafed Sinus & Nasal Decongestant; **Belg.:** Rinomar; Vasocedine Pseudoephedrine; **Canad.:** Benlyn D, Congest Aid, Contac Cold Nasal Congestion Nondrowsy, Decongestant Tablets; Drixoral ND; Eltor; Nasal & Sinus Relief; PseudoFirst; Sudafed Decongestant; Tantafed; Triaminic Allergy Congestion; Triaminic Pediatric Drops; **Chile:** Asafen Nueva Formula; Dexan; **Cz.:** Nurofen Stopgrip; **Fr.:** Ephedroisid; Sudafed; **Hong Kong:** Logicin Sinus; Vidadrine; **India:** Sudafed; **Indon.:** Alco; Disudrin; Non Triaminic; Sudafed; **Isl.:** Sudafed; **Israel:** Alafai Triptipot; Otrinal; Sinufed; Sinufed Kid Day; Tarophed; **Ital.:** Narxan; **Mex.:** Dofedrin; Subofen; Sudafed; **NZ:** Dimetapp Sinus; Sudafed 12 Hour Relief; Sudafed for Children; Sudafed Sinus & Nasal Decongestant; Sudomyl; **Pol.:** Sudafed; **Port.:** Sudafed; **S.Afr.:** Acunaso; Adco-Sufedrin; Demazin Decongestant; Drixil; Drixinal S; Flutex Decon-Sp; Monofed; Sinumed; Sudafed Sinus; Symptofed; **Singapore:** Sudafed; **Spain:** Neodurasinaf; Reactine Plus; **Switz.:** Otrinal; **Thal.:** Sudosian; **Turk.:** Eksöfed; Rinogest; Sudafed; **UAE:** Sedofan II; **UK:** Contac Non Drowsy; Galsud; Meltus Decongestant; Non-Drowsy Sudafed Decongestant; **USA:** Afrin; Allermed; Cenefed; Childrens Sudafed Nasal Decongestant; Congesta; Decofed; Defed; Dimetapp Decongestant; Dorcol Children's Decongestant; Drixoral Non-Drowsy Formula; Efidac 24 Pseudoephedrine; EliSure Childrens Congestion; Genaphed; Halofed; Kid Kare Pediatric Nasal Decongestant; Medi-First Sinus Decongestant; Mini Pseudo; Nasofed; PediaCare Infant's Decongestant; Pseudo; Pseudo-Gest; Seudotabs; Silfedrin; Simply Stuffy; Sinustop Pro; Sudafed; Triaminic Allergy Congestion; Triaminic AM Decongestant Formula; Triaminic Infant Oral Decongestant; Unifed.

**Multi-ingredient:** numerous preparations are listed in Part 3.

## Senega Root

Észak-amerikai-szenegagyökér; Polígala Raíz; Polygala, racine de; Polygalae radix; Putokšlių šaknys; Raíz de polígala; Rattlesnake Root; Seneca Snakeroot; Senega; Seneganiujuri; Senegarot; Vítodový kořen.

Истоа Сегера

ATC — R05CA06.

ATC Vet — QR05CA06.

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

*Jpn* also describes the powdered root.

**Ph. Eur. 6.2** (Senega Root). The dried and usually fragmented root and root crown of *Polygala senega* or certain closely related species of *Polygala* or a mixture of these. It has a faint, sweet odour, slightly rancid or reminiscent of methyl salicylate. Protect from light and humidity.

## Profile

Senega root has been used as an expectorant in oral preparations for respiratory-tract disorders.

*Polygala amara* is a related species that is used similarly.

## Preparations

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

**Multi-ingredient:** **Arg.:** Antitos; Hebert Caramelos; Ixana; No-Tos Adultos; No-Tos Infantil; Pectobron; **Austral.:** Asa Tones; Senegar; Senega and Ammonia; **Austria:** Eicebaer; Tussimont; **Belg.:** Saintbois; Tux; **Braz.:** Expectomel; Limao Bravo; Melagrão; Pectal; **Canad.:** Bronchial; Bronchial Cough; Sirop Cocilana Codeine; Sirop Cocilana Compose; Vampole Bronchial Cough Syrup; **Cz.:** Stodal; **Fr.:** Neo-Codion; **Ger.:** Asthma 6-NH; **Hong Kong:** Coci-Fedra; Coci-Fedra-C; Cocilana Christol; Cocilana Compound; Dextrocilla; Eurocilla; Mefedra-NH; Mist Expect Stim; Pectoral; **Ital.:** Altuss; **Port.:** Calmarum; Stodal; **Rus.:** Neo-Codion Babies (Нео-Кодион Для Малышей); **S.Afr.:** Borstel Cough Remedy; **Spain:** Broncovital; Pastillas Pectoral Kely; Pulmofasa; **Swed.:** Cocilana-Etlyn; **Switz.:** Bronchofluid NH; Expectorant Codein; Expectorant; Foral; Hedelix; Liberoil Pastilles contre la toux; Liberoil Sirop contre la toux; Makaphyt Gouttes antitussives; Makaphyt Sirop; Pectocalmine; Pectoral N; Phol-Tux; **UK:** Antibron; Chest Mixture; Chesty Cough Relief; Tickly Cough & Sore Throat Relief; **Venez.:** Acetoben; Corsaben; Dromil Saucos; Isacol; Novacodin; Yerba Santa.

## Sobrerol

Ciclidrol; Cyclidrol; Sobreroli; Sobrerolo; Sobrerolum. *p*-Menth-6-ene-2,8-diol.

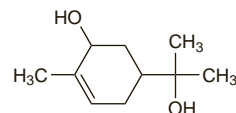
Собрепол

C<sub>10</sub>H<sub>18</sub>O<sub>2</sub> = 170.2.

CAS — 498-71-5.

ATC — R05CB07.

ATC Vet — QR05CB07.



**Pharmacopoeias.** In *It.*

## Profile

Sobrerol is a mucolytic that has been used in respiratory disorders characterised by productive cough (p.1547). Oral doses of up to 800 mg have been given daily in divided doses. Sobrerol has also been given by injection, inhalation, or rectally.

**Pharmacokinetics.** The pharmacokinetics of sobrerol after oral or intravenous doses has been studied in patients with acute exacerbations of chronic bronchitis.<sup>1</sup> Sobrerol was rapidly absorbed from the gastrointestinal tract and rapidly distributed. After intravenous and oral dosage, 13 and 23% of the dose respectively was excreted in the urine as unchanged drug, glucuronidated sobrerol, and hydrated carvone. Sobrerol was shown to accumulate in bronchial mucus.

1. Braga PC, *et al.* Pharmacokinetics of sobrerol in chronic bronchitis: comparison of serum and bronchial mucus levels. *Eur J Clin Pharmacol* 1983; **24**: 209–15.

## Respiratory disorders. References.

1. Bellussi L, *et al.* Evaluation of the efficacy and safety of sobrerol granules in patients suffering from chronic rhinosinusitis. *J Int Med Res* 1990; **18**: 454–9.
2. Azzollini E, *et al.* Sobrerol (Sobrepim®) administered dropwise to children with acute hypersecretory bronchopulmonary disease: a controlled trial v bromhexine. *Clin Trials J* 1990; **27**: 241–9.

## Preparations

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

**Braz.:** Sobrepim; **Hong Kong:** Mucolux; **Ital.:** Sobrepim; Sopulmin; **Malaysia:** Mucolux; **Philipp.:** Mucolux; **Port.:** Broncopulmo; Mucodax; Mucolavil; Pulmus; **Singapore:** Mucolux; **Spain:** Sobrepim; **Thai.:** Mucolux.

**Multi-ingredient:** **Arg.:** Polimucil; **Gr.:** Carbozor; Flemagon; Grupozil; Gutman; Mucostein; Pneumol Plus; Polimucil; Respinorm; Sevelny; Sobrepim; Sorbexyl; Vanesin; **Ital.:** Fluenta; **Port.:** Bronquial; Niflux.