

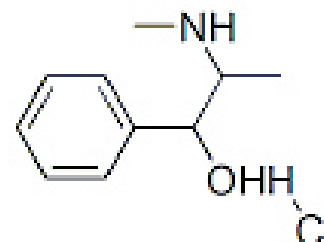
Decongestant

TAJ PHARMACEUTICALS LIMITED

PRODUCT CODE- PSDPHNT612

**PSEUDOEPHEDRINE HCL**Formula C<sub>10</sub>H<sub>16</sub>ClNOCas No. **345-78-8****Pseudoephedrine hydrochloride**

Molecular Formula : C<sub>10</sub>H<sub>16</sub>ClNO  
 Molecular Weight : 201.69  
 CAS No. : 345-78-8

**Chemical Name:**

1. (1S,2S)-2-Methylamino-1-phenyl propan-1-ol, Hydrochloride
2. Benzenemethanol, a-[1-(methylamino)ethyl]-, [S-(R\*,R\*)], Hydrochloride

**Synonyms:**

(+)-PSI-EPHEDRINE HYDROCHLORIDE; PSI-EPHEDRINE HYDROCHLORIDE; PSEUDOEPHEDRINE HCL; PSEUDOEPHEDRINE HCL, (+)-1S,2S-; (+)-PSEUDOEPHEDRINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE; a)-; alpha-(1-(methylamino)ethyl)-, hydrochloride, (s-(r\*, r\*))-benzenemethano; benzenemethanol, alpha-[1-(methylamino)ethyl]-, hydrochloride, [s-(theta, thet; hydrochloride, l-(+)-pseudoephedrin; l-(+)-pseudoephedrine hydrochloride; novafed; sinufed; sudafed; symptom2; tussaphed; D-PSEUDOEPHEDRINE HYDROCHLORIDE; D-ISOEPHEDRINE HYDROCHLORIDE; ISOEPHEDRINE HYDROCHLORIDE; (1S,2S)-2-(METHYLAMINO)-1-PHENYL-1-PROPANOL HYDROCHLORIDE

**Specifications :**

1. Description : Fine, white to off white crystals or powder.
2. Identification : a) Infrared spectrum of sample is concordant with the reference spectrum.  
b) A solution of sample responds to the test for chloride
3. Melting range : Between 182° and 186°C; the range between beginning and end of melting does not exceed 2°C
4. Specific rotation : Between + 61.0° and + 62.5° (5 % solution in water)
5. Solubility : Very soluble in water and freely soluble in alcohol.
6. pH : Between 4.6 and 6.0 (5 % solution in water)
7. Ordinary impurities : NMT 2.0 %
8. Residue on ignition : NMT 0.1 %
9. Loss on drying : NMT 0.5 %
10. Organic volatile impurities : Must pass the test
11. Assay : Between 98.0 % and 100.5 % (dried basis)

Therapeutic indications : Decongestant Packing : Packed in double lined polyethylene bags in 25 kg fiber drums. Storage : Store below 35°C.

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**PSEUDOEPHEDRINE HCL**

Formula C10H16ClNO

Cas No. **345-78-8****Decongestant****Pseudoephedrine**

is a sympathomimetic amine commonly used as a decongestant. The salts pseudoephedrine hydrochloride and pseudoephedrine sulfate are found in many over-the-counter preparations either as single-ingredient preparations, or more commonly in combination with antihistamines, paracetamol (acetaminophen) and/or ibuprofen. Sudafed is a trademark for a common brand which contains pseudoephedrine hydrochloride, though Sudafed PE does not. Cirrus contains pseudoephedrine in conjunction with cetirizine (an antihistamine).

Unlike antihistamines, which relieve multiple allergic symptoms by acting as antagonists at histamine receptors, pseudoephedrine primarily relieves nasal congestion commonly associated with colds or allergies.

The advantage of oral pseudoephedrine over topical nasal preparations, such as oxymetazoline, is that it does not cause rebound congestion (rhinitis medicamentosa); however, it is more likely to cause adverse effects including hypertension.

Pseudoephedrine is being phased out as an over-the-counter drug in some countries and replaced by less effective.

**Chemistry**

Pseudoephedrine is a phenethylamine, and a diastereomer of ephedrine. Pseudoephedrine is a chiral molecule, meaning it occurs in both "left-handed" and "right-handed" configurations which are not superimposable.

Pseudoephedrine is the International Nonproprietary Name (INN) of the (1S,2S)- diastereomer of ephedrine (which has 1R,2S- configuration). Other names are (+)-pseudoephedrine and D-pseudoephedrine.

L-Pseudoephedrine, also known as (-)-(1R,2R)-pseudoephedrine or (-)-pseudoephedrine, is the optical isomer of D-pseudoephedrine. It has fewer side-effects, fewer central nervous system (CNS) stimulatory effects, does not reduce to D-methamphetamine (which is the enantiomer used as a recreational drug), and yet it retains its efficacy as a decongestant.[citation needed] However, the patent holder for L-pseudoephedrine (Pfizer/Warner-Lambert)[has not yet sought or received government approval for its sale to the public.

**Clinical uses****Indications**

**Pseudoephedrine is indicated for the treatment of:**

- \* nasal congestion
- \* sinus congestion
- \* Eustachian tube congestion.

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**PSEUDOEPHEDRINE HCL**

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Cas No. **345-78-8****Decongestant**

Pseudoephedrine is also indicated for vasomotor rhinitis, and as an adjunct to other agents in the optimum treatment of allergic rhinitis, croup, sinusitis, otitis media, and tracheobronchitis.

**Adverse effects**

Common adverse drug reactions (ADRs) associated with pseudoephedrine therapy include: CNS stimulation, sleeplessness, nervousness, excitability, dizziness and anxiety. Infrequent ADRs include: tachycardia and/or palpitations. Rarely, pseudoephedrine therapy may be associated with hallucinations, arrhythmias, hypertension, seizures and ischemic colitis; as well as severe skin reactions known as recurrent pseudo-scarlatina, systemic contact dermatitis, and nonpigmenting fixed drug eruption. Pseudoephedrine, particularly in high doses, may also cause episodes of paranoid psychosis. It has also been reported that pseudoephedrine, amongst other sympathomimetic agents, may be associated with the occurrence of stroke.

This document plus the full buyer / prescribing information, prepared for health professionals can be found at:

<http://www.tajapi.com>

or by contacting the sponsor, Taj Pharmaceuticals Limited., at:  
91 022 30601000.

This leaflet was prepared by  
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Mumbai (India).

**PSDPHNT612**

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The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs.