

PRODUCT CODE- PSDPHT492

 Taj Pharmaceuticals Ltd.  
**Pseudoephedrine**  
**CAS No. 90-82-4**



2508 PSDPH15 89127 0657

## Pseudoephedrine, its salts, optical isomers, and salts of optical isomers

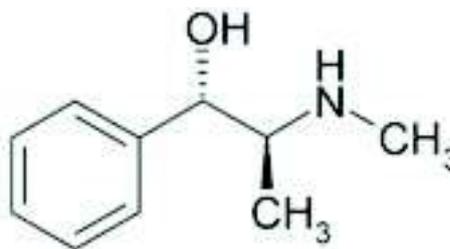
### Identifiers

CAS number : 90-82-4

Formula : C<sub>10</sub>H<sub>15</sub>NO

Mol. Weight : 165.23

Melting Point: 182 - 186 C



**Solubility:** Soluble (soluble in alcohol) RESIDUE Complies

Risk Codes: R20/21/22; R36/37/38 Details

**Appearance:** White fine powder

**Synonyms:** Isoephedrine, trans-Ephedrine, PSEUDOEPHEDRINE, Sudafed, d-Pseudoephedrine, d-Isoephedrine, Psi-ephedrine, Psi-ephedrin, d-psi-Ephedrine, Besan, (+)-Pseudoephedrine, L(+)-psi-Ephedrine, (+)-threo-Ephedrine, (+)-psi-Ephedrine, L-(+)-Pseudoephedrine, Pseudoephedrine (D), (-)-psi-Ephedrine, (-)-Pseudoephedrine, (-)-Pseudoephedrine, Pseudoephedrine, (+)-

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 alternative decongestants such as phenylephrine, due to pseudoephedrine's use as an ingredient in the manufacture of methamphetamine.



## Pharmacokinetic data

Bioavailability unknown  
Metabolism hepatic (10–30%)  
Half life 9–16 hours  
Excretion 70-90% renal

Pseudoephedrine is a decongestant that shrinks blood vessels in the nasal passages. Dilated blood vessels can cause nasal congestion (stuffy nose).

Pseudoephedrine is used to treat nasal and sinus congestion, or congestion of the tubes that drain fluid from your inner ears, called the eustachian (yoo-STAY-shun) tubes.

### Important information about pseudoephedrine

Always ask a doctor before giving a cough or cold medicine to a child. Death can occur from the misuse of cough and cold medicines in very young children. Do not use any other over-the-counter cough or cold medication without first asking your doctor or pharmacist. If you take certain products together you may accidentally take too much of a certain drug. Read the label of any other medicine you are using to see if it contains pseudoephedrine. Do not use a cough or cold medicine if you have used an MAO inhibitor such as isocarboxazid (Marplan), phenelzine (Nardil), rasagiline (Azilect), selegiline (Eldepryl, Emsam), or tranylcypromine (Parnate) within the past 14 days. Serious, life-threatening side effects can occur if you take cough or cold medicine before the MAO inhibitor has cleared from your body.

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## Clinical uses

Pseudoephedrine is indicated for the treatment of:

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

## Mechanism of action

Pseudoephedrine is a sympathomimetic amine—that is, its principal mechanism of action relies on its indirect action on the adrenergic receptor system. While it may have weak agonist activity at  $\alpha$ - and  $\beta$ -adrenergic receptors, the principal mechanism is to cause the release of endogenous norepinephrine (noradrenaline) from storage vesicles in presynaptic neurons. The displaced noradrenaline is released into the neuronal synapse where it is free to activate the aforementioned postsynaptic adrenergic receptors.



These adrenergic receptors are located on the muscles lining the walls of blood vessels. When activated by pseudoephedrine, the muscles contract, causing the blood vessels to constrict (vasoconstriction). These constricted blood vessels now allow less fluid to leave the blood vessels and enter the nose, throat and sinus linings, which results in decreased inflammation of nasal membranes as well as decreased mucus production. Thus, by constriction of blood vessels, mainly those located in the nasal passages, pseudoephedrine causes a decrease in the symptoms of nasal congestion.

The vasoconstriction that pseudoephedrine produces is believed to be principally an  $\alpha$ -adrenergic receptor response. While all sympathomimetic amines, to some extent, have decongestant action, pseudoephedrine shows greater selectivity for the nasal mucosa and a lower affinity for central nervous system (CNS) adrenergic-receptors than other sympathomimetic amines.

Vasoconstriction in the nasal mucosa shrinks swollen nasal mucous membranes, reduces tissue hyperemia, edema, and nasal congestion. Other beneficial effects may include increasing the drainage of sinus secretions, and opening of obstructed Eustachian tubes. The same vasoconstriction action can also result in hypertension, which is a noted side effect of pseudoephedrine.

#### Precautions and contraindications

It is recommended that pseudoephedrine not be used in patients with: diabetes mellitus, cardiovascular disease, hypertension, prostatic hypertrophy, hyperthyroidism, closed angle glaucoma and/or pregnancy

Since nasal congestion is considered to be a relatively minor ailment, alternatives are preferred in patients with these conditions. Appropriate alternatives may include topical decongestants or saline sprays/instillations, depending on the patient's condition.

Contraindications for the use of pseudoephedrine include: concomitant or recent (previous fourteen days) monoamine oxidase inhibitor (MAOI), or serotonin-specific reuptake inhibitor (SSRI) therapy, severe or uncontrolled hypertension, and/or severe coronary artery disease. People with bipolar disorder should use care when taking pseudoephedrine, as it can cause insomnia and thus trigger a manic episode.

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  
Taj Pharmaceuticals Limited,  
Mumbai (India).

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Last revised: 29 August 2009