

Cough and Cold

TAJ PHARMACEUTICALS LIMITED

# Phenylephrine

Formula C<sub>9</sub>H<sub>13</sub>NO<sub>2</sub>Cas No. **61-76-7**

PRODUCT CODE- PPHRNTJ397



## Systematic (IUPAC) name

(R)-3-[-1-hydroxy-2-(methylamino)ethyl]phenol

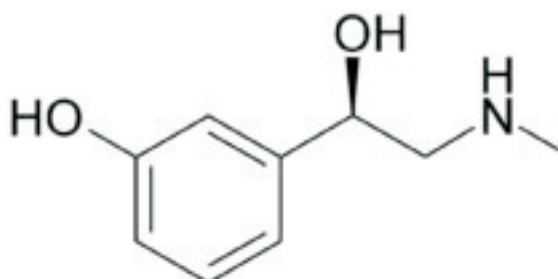
Phenylephrine or Neo-Synephrine is an  $\alpha_1$ -adrenergic receptor agonist used primarily as a decongestant, as an agent to dilate the pupil, and to increase blood pressure. Phenylephrine has recently been marketed as a substitute for pseudoephedrine but there are recent claims that oral phenylephrine may be no more effective as a decongestant than a placebo.

## Chemical data

Formula C<sub>9</sub>H<sub>13</sub>NO<sub>2</sub>

Mol. mass 167.205 g/mol

SMILES eMolecules



## Pharmacokinetic data

Bioavailability 38% through GI tract

Protein binding 95%

Metabolism Hepatic (monoamine oxidase)

Half life 2.1 to 3.4 hours

Routes Oral, intranasal, ophthalmic, intravenous, intramuscular

Phenylephrine is used to relieve nasal discomfort caused by colds, allergies, and hay fever. It is also used to relieve sinus congestion and pressure. Phenylephrine will relieve symptoms but will not treat the cause of the symptoms or speed recovery. Phenylephrine is in a class of medications called nasal decongestants. It works by reducing swelling of the blood vessels in the nasal passages.

## Uses

Phenylephrine comes as a tablet, a liquid, or a dissolving strip to take by mouth. It is usually taken every 4 hours as needed. Follow the directions on your prescription label or the package label carefully, and ask your doctor to explain any part you do not understand. Take phenylephrine exactly as directed.

Phenylephrine comes alone and in combination with other medications. Check nonprescription cough and cold product labels carefully before using two or more products at the same time. These products may contain the same active ingredient(s) and taking them together could cause you to receive an overdose. This is especially important if you will be giving cough and cold medications to a child.

If you are giving phenylephrine or a combination product that contains phenylephrine to a child, read the package label carefully to be sure that it is the right product for a child of that age. Do not give phenylephrine products that are made for adults to children.

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Before you give a phenylephrine product to a child, check the package label to find out how much medication the child should receive. Give the dose that matches the child's age on the chart. Ask the child's doctor if you don't know how much medication to give the child.

Phenylephrine may cause side effects.

\* nervousness

\* dizziness

\* sleeplessness

Phenylephrine is sometimes used as a vasopressor to increase the blood pressure in unstable patients with hypotension. Such use is more common in anesthesia or critical-care practices; phenylephrine is especially useful in counteracting the hypotensive effect of epidural and subarachnoid anesthetics. It also has the advantage of not being inotropic or chronotropic, and so it strictly elevates the blood pressure without increasing the heart rate or contractility (reflex bradycardia may result from the blood pressure increase, however). This is especially useful if the heart is already tachycardic and/or has a cardiomyopathy. The elimination half life of phenylephrine is about 2.5 to 3 hours.

**Substitute for pseudoephedrine**

Pseudoephedrine and phenylephrine are both used as decongestants; and, until recently, pseudoephedrine was much more commonly available in the United States. This has changed because provisions of the Combat Methamphetamine Epidemic Act of 2005 placed restrictions on the sale of pseudoephedrine products in order to prevent the clandestine manufacture of methamphetamine. Since 2004, phenylephrine has been increasingly marketed as a substitute for pseudoephedrine; some manufacturers have changed the active ingredients of products to avoid the restrictions on sales. Phenylephrine has been off patent for some time, and there are many generic brands available.

**Clinical Pharmacology**

Phenylephrine is sympathomimetic vasoconstrictor that has been used as a nasal decongestant for many years. Phenylephrine has one chiral centre and can exist as either the S(+) or R(-) enantiomer. The R(-) enantiomer is the one used in products containing phenylephrine. It is a relatively selective alpha-adrenoceptor agonist. The majority of the sympathomimetic action is due to direct stimulation of the adrenoceptors and relatively little is due to an indirect effect via release of noradrenaline [1]. Its pressor action is weaker than that of noradrenaline but of longer duration [4]. At therapeutic doses, it does not cause significant stimulation of the central nervous system.

Sympathomimetic decongestants reduce the nasal congestion due to increased nasal blood flow associated with colds and influenza. This effect forms the therapeutic basis for their use in these conditions.

Hypertensive patients should be aware of the possible side effects of nonprescription medications on blood pressure control. For absolute safety no adrenergic agents should be used. However, when required, phenylephrine is the safest of these agents. Studies assessing the hypertensive effect of oral phenylephrine in normotensive volunteers have demonstrated that the minimal dose required to elicit an increase in blood pressure is approximately 50 mg that is five times the therapeutic dose.

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Doses in excess of 120 mg are required to elicit a significant effect on blood pressure. A recent study in normotensive volunteers demonstrated that following administration of a cold relief product containing phenylephrine 10 mg and caffeine 60 mg, there was a small but statistically significant increase in total peripheral resistance but no consistent effect on other cardiovascular parameters including heart rate and blood pressure.

**Interactions**

The coadministration of Monoamine Oxidase Inhibitors (MAOIs) or tricyclic antidepressants and an indirect or mixed-acting sympathomimetic may result in a hypertensive crisis. Direct-acting sympathomimetics appear to interact minimally, if at all [16 - Drug Interaction Facts, 4th edition]. Such concomitant use is clearly identified as a contra-indication on the labelling of all phenylephrine-containing products and the appropriate warnings are provided. Additionally sympathomimetics may reduce the efficacy of beta-blocking and anti-hypertensive drugs. Conditions where these drugs are used are contra-indicated for the product.

**Storage/Stability/Compatibility**

The injectable product should be stored protected from light. Do not use solutions if they are brown or contain a precipitate. Oxidation of the drug can occur without a color change. To protect against oxidation, the air in commercially available ampules for injection is replaced with nitrogen and a sulfite added.

Phenylephrine is reported to be compatible with all commonly used IV solutions and the following drugs: chloramphenicol sodium succinate, dobutamine HCl, lidocaine HCl, potassium chloride, and sodium bicarbonate. While stated to be incompatible with alkalies, it is stable with sodium bicarbonate solutions. Phenylephrine is reported to be incompatible with ferric salts, oxidizing agents, and metals.

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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**PHPRNTJ397**

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**Note:** These API/ chemicals are designated as those that are used in the manufacture of the controlled substances and are important to the manufacture of the substances.

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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**



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