

Analgesic, Antitussive

TAJ PHARMACEUTICALS LIMITED

PRODUCT CODE- CPHHYT714

# Codeine phosphate hemihydrate

Formula C<sub>18</sub>H<sub>24</sub>NO<sub>7</sub>PCas No. **41444-62-6**

Codeine phosphate hemihydrate

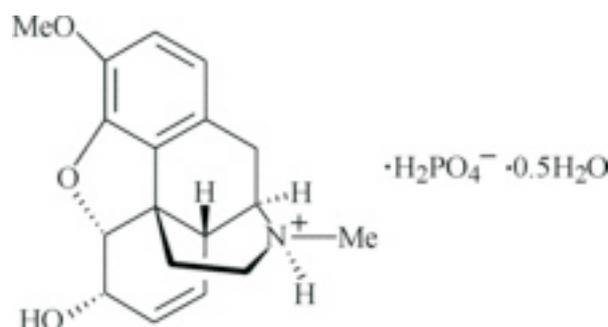
CAS No.: 41444-62-6

Molecular Formula: C<sub>18</sub>H<sub>24</sub>NO<sub>7</sub>P

Formula Weight: 397.36

Mol weight : 406.4

Chemical Name : CODEINE PHOSPHATE



Synonyms: N-METHYLNORCODEINE HEMIHYDRATE; MORPHINE-3-METHYL ETHER HEMIHYDRATE; CODEINE PHOSPHATE; CODEINE PHOSPHATE HEMIHYDRATE; CODEINIUM PHOSPHATE HEMIHYDRATE; METHYLMORPHINE PHOSPHATE HEMIHYDRATE; Morphinan-6-ol, 7,8-didehydro-4,5-epoxy-3-methoxy-17-methyl-, (5.alpha.,6.alpha.)-, phosphate (salt), hydrate (2:2:1); CODEINEPHOSPHATE, USP; Codein phosphate hemihydrate; Codeine-phosphoric acid·0.5hydrate

## CHARACTERS

Appearance: white or almost white, crystalline powder or small, colourless crystals.

Solubility : freely soluble in water, slightly soluble in ethanol (96 per cent).

## History

Codeine is an alkaloid found in opium and other poppy saps like *Papaver bracteatum*, the Iranian poppy, in concentrations ranging from 0.3 to 3.0 percent. While codeine can be extracted from opium, most codeine is synthesized from morphine through the process of O-methylation. It was first isolated in 1832 in France by Jean-Pierre Robiquet.

The effects of the Nixon War On Drugs by 1972 or so had caused across-the-board shortages of illicit and licit opiates because of a scarcity of natural opium, poppy straw and other sources of opium alkaloids, and the geopolitical situation was getting less helpful for the United States. After a large percentage of the opium and morphine in the US National Stockpile of Strategic & Critical Materials had to be tapped in order to ease severe shortages of medicinal opiates—the codeine-based antitussives in particular—in late 1973, researchers were tasked with and quickly succeeded in finding a way to synthesize codeine and its derivatives and precursors from scratch from petroleum or coal tar using a process developed at the United States' National Institutes of Health.

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**Codeine phosphate hemihydrate**Formula C<sub>18</sub>H<sub>24</sub>NO<sub>7</sub>PCas No. **41444-62-6****Analgesic, Antitussive****SIDE EFFECTS**

The most frequent adverse reactions include lightheadedness, dizziness, sedation, nausea, and vomiting. These effects seem to be more prominent in ambulatory than in non ambulatory patients, and some of these adverse reactions may be alleviated if the patient lies down.

Other adverse reactions include euphoria, dysphoria, constipation, and pruritus.

**Drug Abuse and Dependence**

Controlled Substance: Codeine phosphate is a Schedule II narcotic.

**Dependence**

Although much less potent in this regard than morphine, codeine can produce drug dependence a.d. therefore, has the potential for being abused. Patients given 60 mg codeine every 6 hours for 2 months usually show some tolerance and mild withdrawal symptoms. Development of the dependent state is recognized by an increased tolerance to the analgesic effect and the appearance of purposive phenomena (complaints, pleas, demands, or manipulative actions) shortly before the time of the next scheduled dose. A patient in withdrawal should be treated in a hospital environment. Usually, it is necessary only to provide supportive care with administration of a tranquilizer to suppress anxiety. Severe symptoms of withdrawal may require administration of a replacement narcotic.

**INTERACTION**

Carbamazepine, hydantoins, sulfinpyrazone

May result in increased risk of hepatotoxicity.

Cimetidine

Effects of codeine may be enhanced, increasing toxicity.

CNS depressants (eg, barbiturates, ethyl alcohol, other narcotics)

May result in additive CNS depressant effects and toxicity.

Tricyclic antidepressants, phenothiazines

May cause additive CNS depressant effects and toxicity.

**Laboratory Test Interactions**

With Chemstrip bG , Dextrostix , and Visidex II home blood glucose systems, drug may cause false decrease in mean glucose values. False-positive results may occur in urinary 5-hydroxy-indoleacetic acid test.

**USES:** This medication is used to treat mild to moderately severe pain. Codeine phosphate is a narcotic pain reliever. It acts on certain centers in the brain to give you pain relief.

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## Relation to other opiates

Codeine is the starting material and prototype of a large class of mainly mild to moderately strong opioids such as hydrocodone, dihydrocodeine and its derivatives such as nicocodeine. Other series of codeine derivatives include isocodeine and its derivatives, which were developed in Germany starting around 1920. Related to codeine in other ways are Codeine-N-Oxide (Genocodeine), related to the nitrogen morphine derivatives as is codeine methobromide, and heterocodeine which is a drug six times stronger than morphine and 72 times stronger than codeine due to a small re-arrangement of the molecule, viz. moving the methyl group from the 3 to the 6 position on the morphine carbon skeleton. Drugs bearing resemblance to codeine in effects due to close structural relationship are variations on the methyl groups at the 3 position including ethylmorphine a.k.a. codethyline (Dionine) and benzylmorphine (Peronine). While having no narcotic effects of its own, the important opioid precursor thebaine differs from codeine only slightly in structure. Pseudocodeine and some other similar alkaloids not currently used in medicine are found in trace amounts in opium as well.

Codeine is also available in conjunction with the anti-nausea medication promethazine in the form of a syrup. Brand named as Phenergan with Codeine or generically as promethazine with codeine this medication is quickly becoming one of the most highly abused codeine preparations.

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).

**CPHHYT714**

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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.