


**Codeine base CAS No. : 50-98-6**

Ephedrine (EPH) is a sympathomimetic amine commonly used as a stimulant, appetite suppressant, concentration aid, decongestant, and to treat hypotension associated with anaesthesia. Ephedrine is similar in structure to the synthetic derivatives amphetamine and methamphetamine. Chemically, it is an alkaloid derived from various plants in the genus Ephedra (family Ephedraceae). It is most usually marketed in the hydrochloride and sulfate forms.

Active Pharmaceuticals Ingredients Manufacturers


**Taj Pharmaceuticals Ltd.**  
**Codeine base**  
**CAS No. : 76-57-3**
**PRODUCT IDENTIFICATION**

CAS NO. : 76-57-3 (Base) 1422-07-7 (Hydrochloride)  
 FORMULA : C<sub>18</sub>H<sub>21</sub>NO<sub>3</sub>  
 MOL WT. : 317.38

DERIVATION TOXICITY : Oral rat LD50: 427 mg/kg

**SYNONYMS**

Methyl morphine monohydrate;  
 7,8-Didehydro-4,5- $\alpha$ -epoxy-3-methoxy-17-methylmorphinan- 6- $\alpha$ -ol;  
 3-o-methylmorphine Monohydrate; 7,8-Didehydro-4,5-epoxy-3-methoxy-  
 17-methyl-(5 $\alpha$ , 6 $\alpha$ )-morphinan 6-ol; Actacode; Calcidrine; Codicept; Codalgin  
 Forte Codate; (-)-Codeine; Codeinum; Coducept; Metilmorfina; Morphine-3-methyl  
 ether; Morphine monomethyl ether; N-Methyl Norcodine;

**CLASSIFICATION****PHYSICAL AND CHEMICAL PROPERTIES**

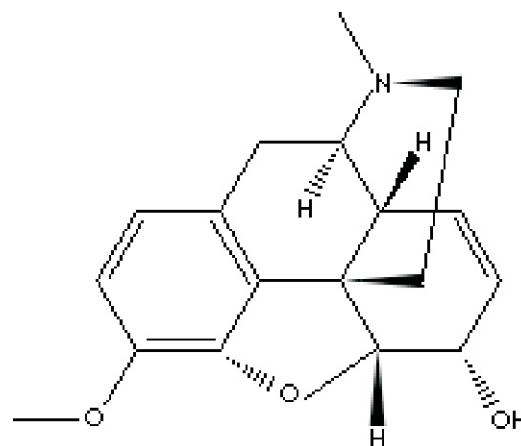
PHYSICAL STATE : white crystalline powder  
 MELTING POINT : 154 - 156 C  
 BOILING POINT : 250 C  
 SPECIFIC GRAVITY : 1.32  
 SOLUBILITY IN WATER : pH  
 VAPOR DENSITY : AUTOIGNITION  
 NFPA RATINGS : Health: 3 Flammability: 1 Reactivity: 1  
 FLASH POINT : 75 C  
 STABILITY : Stable under ordinary conditions  
 Odor : None found  
 Taste : None found

**DESCRIPTION**

Codeine is an alkaloid found naturally in opium in concentrations ranging from 0.7 to 2.5 percent. It is commercially synthesized from morphine. It is the most widely used drug among the morphine class of compounds used in a variety of pharmaceuticals including analgesics, antiperistaltics, antitussive agents, hypnotics, and sedatives. Codeine is an opioid analgesic related to morphine but with less potential analgesic property and mild sedative effect. Dihydrocodeine, called also drocode, is a similar opioid analgesic with pharmaceutical action with codeine. It is known it has approximately twice potentiality.

**SPECIFICATION :**

APPEARANCE : white crystalline needles  
 PURITY : 99.0% min (Dry Basis)  
 OPTICAL ROTATION : -106° ~ -110° (C=1 in water)  
 WATER : 10.0% max  
 TRANSPORTATION PACKING : HAZARD CLASS UN NO.  
 OTHER INFORMATION : Hazard Symbols: , Risk Phrases: 20/21/22, Safety Phrases: 26-36





TAJ PHARMACEUTICALS LIMITED

## **CODEINE BASE**

Formula C<sub>18</sub>H<sub>21</sub>NO<sub>3</sub>

Cas No. **76-57-3**

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.

Numerous codeine salts have been prepared since the drug was discovered. The most commonly used are the hydrochloride (freebase conversion ratio 0.805), phosphate (0.736), sulphate (0.859) and citrate (0.842). Others include a salicylate NSAID, codeine salicylate (0.686), and at least four codeine-based barbiturates, the cyclohexenylethylbarbiturate (0.559), cyclopentenylallylbarbiturate (0.561), diallylbarbiturate (0.561), and diethylbarbiturate (0.619).

### **Uses**

Codeine is an opiate used for its analgesic, antitussive, and antidiarrheal properties. Codeine is useful for numbing back pain, and is frequently prescribed for this purpose. Codeine is by far the most widely used opiate in the world and probably the most commonly used drug overall according to numerous reports over the years by organizations such as the World Health Organization and its League of Nations predecessor agency and others. It is one of the most effective orally-administered opioid analgesics and has a wide safety margin



### **Safety Profile**

A human poison by an unspecified route. An experimental poison by ingestion, intraperitoneal, intravenous, intramuscular, and subcutaneous routes. Human reproductive effects. An experimental teratogen. Other experimental reproductive effects. An addictive drug. Flammable when exposed to heat or flame. To fight fire, use alcohol foam. When heated to decomposition it emits toxic fumes of Nox.

### **Hazards Identification**

**DANGER! MAY BE FATAL IF SWALLOWED. HARMFUL IF INHALED OR ABSORBED THROUGH SKIN. ALLERGEN. EXPOSURE MAY PRODUCE ALLERGIC RESPONSE. NARCOTIC.**

### **Inhalation:**

Narcotic. Can irritate the respiratory passages and cause sneezing or coughing but will also have an anesthetic effect. Inhalation of appreciable quantities may produce lung edema, dizziness, and respiratory difficulties, see also Ingestion, below.

### **Ingestion:**

Toxic. Narcotic. Human lethal dose about 800 mg. In addition to its analgesic action, codeine can cause slow respiration, cyanosis, weak pulse, gastrointestinal spasm, pinpoint pupils and twitching or convulsions. Death from respiratory failure can occur.



**Skin Contact:** Not expected to cause health effects, although the possibility of absorption exists under conditions of skin breakage or inflammation.

**Eye Contact:** Mild irritant but will also have a strong narcotic effect (pupil constriction) and the eye may serve as an absorption route to the body in general.

**Chronic Exposure:** Can lead to habituation and addiction. Pinpoint pupils and rapid changes of mood may be observed.

**Aggravation of Pre-existing Conditions:** Some individuals may become sensitized from exposure and develop skin rashes, coughs, stuffy nose, asthma, and other allergic complaints. Sensitivity may develop soon after immediate contact or after years of exposure.

#### **First Aid Measures :**

**Inhalation:** Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.

**Ingestion:** Induce vomiting immediately as directed by medical personnel. Never give anything by mouth to an unconscious person.

**Skin Contact:** Immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Call a physician, immediately. Wash clothing before reuse.

**Eye Contact:** Immediately flush eyes with plenty of water for at least 15 minutes, lifting lower and upper eyelids occasionally. Get medical attention immediately.

#### **Fire Fighting Measures**

**Fire:** As with most organic solids, fire is possible at elevated temperatures or by contact with an ignition source.

**Explosion:** Not considered to be an explosion hazard.

**Fire Extinguishing Media:** Water spray, dry chemical, alcohol foam, or carbon dioxide.

**Special Information:** In the event of a fire, wear full protective clothing and NIOSH-approved self-contained breathing apparatus with full facepiece operated in the pressure demand or other positive pressure mode.

#### **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. For any (Control Substance) products Import and Export \*\*\* subjected to your country government laws /control substance ACT.

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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.

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.

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