

Dihydrocodeine hydrogentartrate Cas No. : 5965-13-9

Dihydrocodeine is used to treat moderate to severe pain.

Active Pharmaceuticals Ingredients Manufacturers

Taj Pharmaceuticals Ltd.**Dihydrocodeine hydrogentartrate****CAS No. : 125-30-4****Synonyms**

Paracodeine bitartrate

Morphinan-6-ol, 4,5-epoxy-3-methoxy-17-methyl-, (5.alpha.,6.alpha.)-, [R-(R*,R*)]-2,3-dihydroxybutanedioate (1:1) (salt)

Codeine, dihydro-, tartrate (1:1) (6CI,7CI)

Hydrocodeine hydrogen tartrate

4,5alpha-Epoxy-6alpha-hydroxy-3-methoxy-17-methylmorphinan hydrogen (R-(R*,R*))-tartrate

Dihydrocodeine bitartrate

Tuscodin

Morphinan-6alpha-ol, 4,5alpha-epoxy-3-methoxy-17-methyl-, tartrate (1:1) (salt) (8CI)

Morphinan-6.alpha.-ol, 4, 5.alpha.-epoxy-3-methoxy-17-methyl-, tartrate (1:1) (salt)

Morphinan-6-alpha-ol, 4,5-alpha-epoxy-3-methoxy-17-methyl-, tartrate (1:1)

CAS Number:5965-13-9

Molecular Formula:C18H23NO3

Molecular Weight:451.47

EINECS:204-732-3

Density:1.31 g/cm3

Boiling Point:462 °C at 760 mmHg

DOSAGE

Take dihydrocodeine exactly as directed by your doctor.

If you have been supplied the modified release tablets, they should be swallowed whole (not crushed or chewed) with a glass of water.

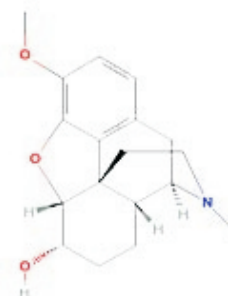
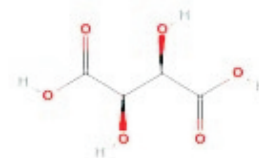
Dihydrocodeine should be taken with or after food. If however you are taking the modified release form of dihydrocodeine this can be taken without food. Take this medication by mouth with or without food or as directed by your doctor. This medication may be taken with food or milk if stomach upset occurs. Drink plenty of fluids when you use this medication unless otherwise directed by your doctor. The fluid will help loosen the mucus in your lungs.

If you are using the liquid form, use a medication-measuring device or spoon to carefully measure the prescribed dose. Do not use a household spoon because you may not get the correct dose. If your liquid form is a suspension, shake the bottle well before each dose.

Dosage is based on your medical condition, age, and response to treatment. If you are extremely drowsy after using this medication, consult your doctor or pharmacist promptly. Your dosage may need to be lowered.

This medication may cause dependence, especially if it is used regularly for an extended time (more than a few weeks) or if it is used in high doses. In such cases, if you suddenly stop this drug, withdrawal reactions may occur. Such reactions can include restlessness, sweating, chills, nausea, vomiting, and diarrhea. Report any such reactions to your doctor immediately. When stopping extended, regular treatment with this drug, gradually reducing the dosage as directed will help prevent withdrawal reactions. Consult your doctor or pharmacist for more details.

Rarely, abnormal drug-seeking behavior (addiction) is possible with this medication. Do not increase your dose, take it more frequently, or use it for a longer time than prescribed. Properly stop the medication when so directed.



Taj Pharmaceuticals Ltd.

Dihydrocodeine hydrogentartrate

CAS NO- 5965-13-9

SIDE EFFECTS

Along with their useful effects all medicines can cause unwanted side effects, which usually improve as your body adjusts to the new medicine. Speak with your doctor or pharmacist if any of the following side effects continue or become troublesome. Common side-effects What can I do if I experience this Feeling or being sick Drink plenty of liquid. Stick to simple foods such as dry toast. If vomiting continues to be a problem speak to your doctor. Constipation Try to eat a well balanced diet containing plenty of fibre and drink 6-8 glasses of water each day. If constipation continues to be a problem speak to your pharmacist or doctor. Drowsiness, dizziness Make sure your reactions are normal before driving, operating machinery or doing any other jobs which could be dangerous if you were not fully alert or feel dizzy. Avoid alcohol; it will increase any feelings of drowsiness Dry mouth Try chewing sugar-free gum, sucking pieces of ice or sugar-free sweets. If this becomes troublesome speak to your pharmacist or doctor. Sweating Use a cold wet flannel to cool yourself down, if this continues to be problem and prevents you from taking your medicine, speak with your doctor. Difficulty urinating (passing water), flushing (redness of the face), a fast or fluttering heartbeat, seeing or hearing things that aren't real, mood changes, sexual problems or skin rashes Speak with your doctor.

PRECAUTIONS

- # Keep all medicines out of the sight and reach of children.
- # Make sure that the person prescribing this medicine knows about any other medicines that you are taking. This includes medicines you buy and herbal and homeopathic medicines.
- # If you buy any medicines check with a pharmacist that they are safe to take with your other medicines.
- # Before taking this medicine tell your doctor if you have ever had an allergic reaction after taking any medicine.
- # Never take more than the prescribed dose. If you suspect that you or someone else has taken an overdose of this medicine go to the accident and emergency department of your local hospital at once. Always take the container with you, if possible, even if it is empty.
- # If you are having any treatment like an operation or dental treatment tell the person carrying out the treatment which medicines you are taking.
- # Always read the printed information leaflet that comes with your medicine.
- # This medicine is for you. Never give it to other people even if their condition appears to be the same as yours.
- # Never keep out of date or unwanted medicines. Take them to your local pharmacy which will dispose of them for you.
- # If you have any questions about this medicine ask your pharmacist.

INTERACTION

This drug should not be used with the following medications because very serious, possibly fatal interactions may occur: MAO inhibitors (e.g., furazolidone, isocarboxazid, linezolid, moclobemide, phenelzine, procarbazine, rasagiline, selegiline, tranylcypromine). If you are currently using any of these medications listed above, tell your doctor or pharmacist before starting this medication. Avoid taking MAO inhibitors within 2 weeks before, during, and after treatment with this medication. Before using this medication, tell your doctor or pharmacist of all prescription and nonprescription/herbal products you may use, especially of: drugs for high blood pressure (e.g., methyl dopa, reserpine, beta blockers such as metoprolol and atenolol), cimetidine, narcotic antagonists (e.g., naltrexone, naloxone). Tell your doctor or pharmacist if you also take drugs that cause drowsiness such as: certain antihistamines (e.g., diphenhydramine), anti-seizure drugs (e.g., carbamazepine), medicine for sleep or anxiety (e.g., alprazolam, diazepam, zolpidem), muscle relaxants, narcotic pain relievers (e.g., codeine), psychiatric medicines (e.g., chlorpromazine, risperidone, amitriptyline, trazodone).

Check the labels on all your medicines (e.g., cough-and-cold products, diet aids) because they may contain the same or similar ingredients that could increase your heart rate or blood pressure or cause drowsiness. Ask your pharmacist about using those products safely.

DRUG DESCRIPTION

Dihydrocodeine, also called DHC, Drocode, Paracodeine and Parzone and by the brand names of Synalgos DC, Panlor DC, Panlor SS, Contugesic, SS Bron, Drocode, Paracodin, Codidol, Didor Continus, Dicogesic, Codhydrine, Dekacodin, DH-Codeine, Didrater, Dihydrin, Hydrocodin, Nadeine, Novicodin, Rapacodin, Rikodeine, Fortuss, Remedeine, Dico, and DF-118 amongst others (e.g. PARAMOL), is a semi-synthetic opioid analgesic developed in Germany in the first decade of the 20th Century and put on the market in 1911. It is prescribed for postoperative pain, severe dyspnea, or as an antitussive. Dihydrocodeine tartrate is also present in co-dydramol. In some countries, controlled-release dihydrocodeine and/or the immediate release formulations are used as an alternative to methadone in treatment of opioid dependency and addiction. Commonly available as tablets, solutions, elixirs, and other oral forms, dihydrocodeine is also available in some countries as an injectable solution for deep subcutaneous and intra-muscular administration. Intravenous administration could be dangerous due to pulmonary oedema and the potential of anaphylaxis as it is with codeine. At one time in the past and possibly now, dihydrocodeine suppositories also existed.

Dihydrocodeine is used as an alternative to or incrementation on codeine for the above mentioned spectrum of situations. It is available as the following salts, in rough descending order of frequency of use: bitartrate, phosphate, hydrochloride, tartrate, hydroiodide, methyl iodide, hydrobromide, and sulfate. The salt to free base conversion factors are 0,67 for the bitartrate, 0,73 for the phosphate, and 0,89 for the hydrochloride.

Dihydrocodeine was developed during the intense international search for more effective antitussives, especially to help reduce the airborne spread of tuberculosis, pertussis, pneumonia, and similar diseases, in the years from c.a. 1895 to 1915, and is similar in chemical structure to codeine. Depending on individual metabolism, dihydrocodeine is 100 to 150 percent as strong as codeine [citation needed]. Although dihydrocodeine does have extremely active metabolites, in the form of dihydromorphine and dihydromorphine-6-glucuronide (one hundred times more potent), these metabolites are produced in such small amount that they do not have clinically important effects.



Note /Government Notification: These 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:

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

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