Codeine – Patient Information Sheet

Codeine is a narcotic analgesic and due to its Codeine content it is very useful in the symptomatic treatment of muscular pains, postoperative and postnatal pains, rheumatic pains, lumbago, neuralgia, sciatica, torticollis, menstrual cramps, cephalalgia, toothaches and pains caused by a neoplastic process.

**Before Using Codeine**

**Contraindications of Codeine**

Hypersensitivity to paracetamol or codeine. Hepatic diseases. Any degree of respiratory depression due to the depressor effect of codeine. It must not be administered to children of less than 15 years of age.

**Precautions when taking Codeine**

Codeine should be administered with precaution to patients with impaired renal or hepatic function, anaemia, or with cardiac or pulmonary conditions. Like all analgesics, prolonged treatment with should be avoided unless recommended by your doctor. Do not to exceed the recommended dose.

**Abuse and dependance with Codeine**

Like other major analgesics, the prolonged and excessive administration of codeine, may lead to psychic dependence, physical dependence and tolerance, with abstinence symptoms as a consequence of abrupt withdrawal of this medication. For this reason, Codeine must be prescribed and administered with the same degree of precaution as other opioid analgesics, particularly, in patients with abuse and addiction tendency. After prolonged treatments, administration should be discontinued gradually under medical surveillance.

**Codeine special warnings**

Use during pregnancy and lactation: Codeine is not recommended during pregnancy or lactation, if administered, it must only be if prescribed by your
doctor, who should weigh the potential benefits against the possible risks to mother and child. Do not exceed the recommended dosage.

**Effects on the ability to drive with Codeine:**

Codeine may impair the ability to drive, operate hazardous machinery and, in general when carrying out activities in which the lack of concentration and skill may be dangerous. Alcohol may potentiate these effects, therefore it is recommended not to consume alcoholic beverages during treatment with Codeine.

**Use in children with Codeine:**

Codeine should not be administered to children of less than 15 years of age.

**Codeine in the elderly:**

The elderly are usually more sensitive to the effects and adverse reactions of Codeine.

**Codeine in sportsmen/women:**

Sportsmen/women should be aware that Codeine contains an ingredient, which may give a positive test result in a doping analysis control.

**Interactions of Codeine**

**Medicamentosus interactions:**

**Codeine related:**

**Contraindicated combinations:**

- Morphine agonists-antagonists like nalbuphine, buprenorphine, and pentazocine.

**Combinations to be avoided:**

Alcohol: potentiates the sedative effect of morphine analgesics. Alcohol consumption and the administration of medications that contain alcohol should be avoided, as they may impair the patient's state of alertness.
Other Central Nervous System depressants: antidepressants, sedatives, antihistamines H1, anxiolytics and hypnotics, neuroleptics, clonidine and related medications, thalidomide. Impairment upon the patient’s state of alertness may affect the ability to drive or operate machinery when this medication is taken at the same time as these Central Nervous System depressants.

Other morphine analgesics, barbiturates, and benzodiazepines: increase the risk of respiratory depression, this can be fatal in the case of an overdose.

Paracetamol related:

Oestrogens (present in oral contraceptives or in medications for post-menopause therapy) may diminish the therapeutic efficacy of paracetamol.

Clinical diagnostics:

Paracetamol related:

The ingestion of paracetamol may interfere with the quantifying of uric acid and glucose serum levels.

Posology

Dosage should be determined by your doctor, depending on the intensity of the pain and characteristics of the pain experienced. In general, 1 tablet should be taken every 6 hours. The maximum dose per intake is 2 tablets and the maximum daily dose is 8 tablets. The administration of this medication depends on the appearance of pain or febrile symptoms, as these start to disappear you should cease taking this medication. In cases of severe renal insufficiency (creatinine clearance less than 10ml. / minute), the total daily dosage should be reduced by 50% and the interval between two doses should be at least 8 hours. In elderly patients, it is recommended to reduce the daily dosage and to leave intervals of a minimum of 8 hours between doses. Do not exceed the recommended dose.

INSTRUCTIONS FOR THE CORRECT ADMINISTRATION OF THE MEDICATION.

Swallow the tablets with a sip of water or other non-alcoholic liquid.
Adverse reactions of with Codeine

Occasionally, allergic reactions like skin rash may appear but disappear when treatment is discontinued. On occasion´s somnolence, nausea and constipation may occur. Exceptionally, and after prolonged treatment, some cases of blood disorders like leucopenia (decrease of leucocytes), neutropenia (decrease of neutrophils), thrombocytopenia (decrease of platelets in the blood, or hemolytic anaemia have been reported. Hepatotoxicity due to paracetamol can be caused by high dosage or prolonged treatments.

If you notice any other adverse reaction not mentioned above, consult your doctor or pharmacist.

Overdose with Codeine and its treatment

In the case of an overdose you should go to a hospital immediately, even if you do not experience any symptoms because they are very serious and are usually manifested as of the third day of ingestion. The period in which the treatment is likely to be more effective is within the 12 hours following the ingestion of the overdose. The ingestion of one dose of more than 6 gr. in adults (12 tablets of with Codeine) and more than 100 mg. per kg. of the body weight in children (4 tablets taken in one dose, for a child of 20 kg.) is considered a paracetamol overdose.

Patients on barbiturate treatments or chronic alcoholics may be more susceptible to the toxicity of a paracetamol overdose.