PRESCRIBING INFORMATION

ⓃCODEINE 15

Codeine Phosphate Tablets, USP
15 mg

ⓃCODEINE 30

Codeine Phosphate Tablets, USP
30 mg

Opioïde Analgésique / Antitussif
Opioid Analgesic/Antitussive

LABORATOIRES TRIANON INC.
Blainville, Quebec
J7C 3V4

www.labriva.com

Date of revision:
October 11, 2013.

Control #: 168114

ACTIONS AND CLINICAL PHARMACOLOGY

Codeine exerts its effect on opiate receptors, primarily in the CNS and smooth muscle. Its effects include: analgesia, respiratory depression, suppression of the cough reflex, decreased gastrointestinal motility. CNS changes and stimulation of the chemoreceptor trigger zone which causes nausea and vomiting.

Pharmacokinetics: Codeine is well absorbed orally and from parenteral sites. Onset of analgesic action occurs in 10 to 30 minutes after parenteral administration or in up to 45 minutes following an oral dose. Peak effect is reached in 30 to 60 minutes after an i.m. or s.c. dose or 1 to 2 hours after oral dosing. Analgesia lasts 4 to 6 hours. Codeine's antitussive effect peaks within 1 to 2 hours and lasts up to 4 hours. Its plasma half-life is approximately 3 to 4 hours but may be as long as 19 hours in anephric patients. Codeine is approximately 7% bound to plasma protein; its volume of distribution is 2.5 to 3.5 L/kg. It is primarily metabolized by the liver, and its metabolites, some active, are eliminated in the urine. Only a small fraction (0.01) is excreted unchanged.

See Annex 1 (opioid analgesics: approximate analgesic equivalence) for the opioid analgesic response equivalent to that from 10 mg of morphine.

INDICATIONS AND CLINICAL USE

For the symptomatic treatment of mild to moderate pain of various causes and the control of exhausting, nonproductive cough which does not respond to non-opioid antitussives.

Pediatrics

Regardless of clinical setting, the use of codeine, including Codeine 15 and Codeine 30, is not recommended in patients below the age of 12 years due to increased safety concerns (see Warnings and Precautions/Special Populations/Pediatrics).

CONTRAINDICATIONS

Codeine 15 and Codeine 30 are contraindicated in:

- Patients who are hypersensitive to the active substance (codeine) or other opioid analgesics or any other ingredient in the formulation. For a complete listing, see the DOSAGE FORMS, COMPOSITION AND PACKAGING section of the Prescribing Information.
- In patients with known or suspected mechanical gastrointestinal obstruction (e.g., bowel obstruction, strictures) or any diseases/conditions that affect bowel transit (e.g., ileus of any type).

- Patients with suspected surgical abdomen (e.g., acute appendicitis or pancreatitis).
- Patients with acute asthma or other obstructive airway, and status asthmaticus.
- Patients with acute respiratory depression, elevated carbon dioxide levels in the blood, and cor pulmonale.
- Patients with acute alcoholism, delirium tremens, and convulsive disorders.
- Patients with severe CNS depression, increased cerebrospinal or intracranial pressure, and head injury.
- Patients taking monoamine oxidase (MAO) inhibitors (or within 14 days of such therapy).
- Women who are pregnant, or during labour and delivery.
- Children under 12 years old

WARNINGS AND PRECAUTIONS

Opioid analgesics have the potential for abuse. Psychological dependence or physical dependence and tolerance may follow repeated administration. Opioid analgesics should be prescribed and administered with caution, especially in cases of severe hepatic insufficiency, severe CNS depression or coma, in patients with head injuries or conditions in which intracranial pressure is increased, myxedema, Addison's Disease, acute alcohol intoxication, delirium tremors, convulsive disorders and in patients taking MAO inhibitors. Opioid analgesics can cause severe hypotension in individuals whose circulation is already compromised by hypovolemia, shock, drugs producing hypotension or other conditions that interfere with ability to maintain normal blood pressure. These drugs may produce orthostatic hypotension in the ambulatory patient.

Ultra-Rapid Metabolizers of Codeine: Some individuals may be ultra-rapid metabolizers due to a specific CYP2D6*2x2 genotype. These individuals convert codeine into its active metabolite, morphine, more rapidly and completely than other people. This rapid conversion results in higher than expected serum morphine levels. Even at labeled dosage regimens, individuals who are ultra-rapid metabolizers may experience overdose symptoms such as extreme sleepiness, confusion, or shallow breathing.

Lactation: Codeine is secreted into human milk. In women with normal codeine metabolism (normal CYP2D6 activity), the amount of codeine secreted into human milk is low and dose-dependent. Despite the common use of codeine products to manage postpartum pain, reports of adverse events in breastfed infants are rare. **However, some women are ultra-rapid metabolizers of codeine (see WARNINGS, Ultra-**

Rapid Metabolizers of Codeine). These women achieve higher-than-expected serum levels of codeine's active metabolite, morphine, leading to higher-than-expected levels of morphine in breast milk and potentially dangerously high serum morphine levels in their breastfed infants. Mothers using codeine should be informed about when to seek immediate medical care and how to identify the signs and symptoms of neonatal toxicity, such as drowsiness or sedation, difficulty breastfeeding, breathing difficulties and decreased tone in their baby. Therefore, maternal use of codeine can potentially lead to serious adverse reactions, including death, in nursing infants.

The prevalence of this CYP2D6*2x2 phenotype varies widely and has been estimated at 0.5 to 1% in Chinese, Japanese and Hispanics, 1 to 10% in Caucasians, 3% in African Americans, and 16 to 28% in North Africans, Ethiopians, and Arabs. Data are not available for other ethnic groups. The risk of infant exposure to codeine and morphine through breast milk should be weighed against the benefits of breastfeeding for both the mother and baby. Caution should be exercised when codeine is administered to a nursing woman. If a codeine containing product is selected, the lowest dose should be prescribed for the shortest period of time to achieve the desired clinical effect. Prescribers should closely monitor mother-infant pairs and notify treating pediatricians about the use of codeine during breastfeeding.

Respiratory

Codeine, including Codeine 15 and Codeine 30, is not recommended for use in any patient in whom respiratory function might be compromised including neuromuscular disorders, severe cardiac or respiratory conditions, lung infections, multiple trauma or extensive surgical procedures.

Before prescribing medication to suppress or modify cough, it is important to ascertain that the underlying cause of the cough is identified, that modification of the cough does not increase the risk of clinical or physiologic complications, and that appropriate therapy for the primary disease is provided.

Use with extreme caution in patients having an acute asthmatic attack, patients with chronic obstructive pulmonary disease or cor pulmonale, patients having a substantially decreased respiratory reserve and patients with preexisting respiratory depression, hypoxia or hypercapnia. Usual therapeutic doses may decrease respiratory drive while simultaneously, increasing airway resistance to the point of apnea. In patients with asthma or pulmonary emphysema, codeine may, due to its drying action on the respiratory mucusa, increase viscosity of bronchial secretions and suppress the cough reflex.

Use with caution in sedated or debilitated patients, in patients who have undergone thoracotomies or laparotomies, since suppression of the cough reflex may lead to retention of secretions postoperatively in these patients.

The respiratory depressant effects of codeine and its capacity to elevate cerebrospinal fluid pressure may be markedly exaggerated in the presence of head injury or intracranial lesions or pre-existing increase in intracranial pressure. Opioids produce adverse reactions which may obscure the clinical course of a patient with head injuries. In such patients, codeine must be used with extreme caution and only if its use is deemed essential.

Use with caution in patients with seizures as they may be exacerbated or induced by opioids.

Use with caution in patients with cardiac arrhythmias due to the cholinergic effects of the drug.

Codeine should be given with caution and the initial dose should be reduced in certain patients such as the debilitated and those with severe impairment of hepatic or renal function, hypothyroidism, Addison's disease, prostatic hypertrophy or urethral stricture.

Pediatrics

In children the respiratory centre is more susceptible to the inhibitory action of opioids. Benefit to risk ratio should be carefully considered especially in children with compromised airways. Estimation of dosage relative to the child's age, weight, and pathophysiological state is of great importance. (See **DOSAGE AND ADMINISTRATION**)

Tolerance, psychological dependence and physical dependence may develop in patients receiving codeine phosphate over a prolonged period.

Geriatrics

Elderly patients may be more susceptible to adverse effects, especially respiratory depression and constipation. Caution is advised; the initial dose should be reduced and effects monitored. Elimination and metabolism may be slowed; lower doses or longer dosing intervals may be required.

The administration of codeine or other opioids may obscure the diagnosis or clinical course in patients with acute abdominal conditions.

Codeine should not be used in patients with diarrhea associated with pseudomembranous colitis.

Use with caution in patients with acute ulcerative colitis or other severe inflammatory bowel disease due to the risk of toxic megacolon.

Caution should be exercised and dosage may need to be reduced when codeine is administered with other drugs which depress the CNS (including alcohol), with MAO inhibitors, phenothiazines or tricyclic

antidepressants.

Occupational Hazards

Warn patients against driving or operating machinery if they become drowsy or show impaired mental and/or physical abilities while taking codeine.

Pregnancy

Since codeine phosphate crosses the placenta barrier, its use in pregnancy is not recommended.

Lactation

Codeine is excreted in small amounts which are probably insignificant with usual analgesic or antitussive doses.

DRUG INTERACTIONS

Anticholinergics: Concomitant use of drugs with antimuscarinic activity may increase the risk of severe constipation and/or urinary retention.

Cimetidine: Concurrent administration of cimetidine may lead to increased effect or toxicity of opioid analgesics.

CNS Agents: Concomitant administration of other CNS drugs such as sedatives, hypnotics, phenothiazines, anesthetics and alcohol may increase the sedative and depressant effects of opioid analgesics. If the concomitant use of these drugs is considered necessary, their doses should be reduced accordingly.

MAO Inhibitors: Serious adverse reactions have been reported in patients who receive MAO inhibitors with pethidine. Other opioid analgesics should be used with extreme caution, if at all, in patients taking MAO inhibitors (including selegiline) or within 14 days of such therapy.

Neuromuscular Blocking Agents: Opioid analgesics may enhance the effects of neuromuscular blocking agents resulting in increased respiratory depression.

Opioid Antagonists: Naltrexone and agonist-antagonist opioid analgesics (i.e., pentazocine, nalbuphine, butorphanol) should not be administered to a patient who has received or is receiving a course of therapy with a pure opioid agonist analgesic. In these patients, mixed agonist-antagonists may reduce the analgesic effect or may precipitate withdrawal symptoms.

Other Opioids: The use of more than one opioid agonist at a time is usually inappropriate; additive CNS

depressant, respiratory depressant and hypotensive effects may occur if 2 or more agonists are used concurrently. Potentiation of effects may occur with a previously administered long-acting opioid analgesic.

Tricyclic Antidepressants: Tricyclic antidepressants may enhance opioid-induced respiratory depression.

Warfarin: Opioid agonists may potentiate the anticoagulant effects of coumarin anticoagulants.

Drug Laboratory Test Interactions: Opioid analgesics may interfere with certain diagnostic procedures, by increasing plasma amylase and lipase concentrations and by increasing CSF pressure. Gastric emptying is delayed by these drugs so gastric emptying studies will not be valid.

ADVERSE REACTIONS

Major: Respiratory depression and respiratory arrest. To a lesser degree circulatory depression, shock and cardiac arrest (see **WARNINGS AND PRECAUTIONS**).

Most Commonly Requiring Medical Attention: Sedation, nausea and vomiting, constipation and sweating. These effects seem to be more prominent in ambulatory patients and in those not experiencing severe pain. In such individuals, lower doses are advisable. Some adverse reactions may be alleviated if the patient lies down.

Cardiovascular: Supraventricular tachycardia, bradycardia, palpitations, faintness, syncope, postural hypotension and hypertension, and phlebitis following i.v. injection.

CNS: Drowsiness, sedation, euphoria, dysphoria, weakness, headache, agitation, seizures, uncoordinated muscle movements, alterations of mood, dreams, hallucinations and disorientation, visual disturbances, insomnia, miosis, toxic psychoses.

Constipation: Practically all patients become constipated while taking opioid analgesics on a persistent basis. In some instances, particularly the elderly or bedridden, patients may become impacted. It is essential to caution patients in this regard and to institute an appropriate regimen of bowel management at the start of prolonged therapy.

Gastrointestinal: Dry mouth, nausea, vomiting, constipation, biliary tract spasm, laryngospasme, anorexia, diarrhea, cramps, dyspepsia, taste alterations.

Genitourinary: Urinary retention or hesitance, antidiuretic effect, reduced libido and/or potency.

Hypersensitivity: Pruritus, urticaria, other skin rashes, edema, diaphoresis, wheal and flare over the vein

with i.v. injection. Because of close structural similarities, patients exhibiting systemic allergy to morphine (e.g., generalized rash, shortness of breath) should not receive codeine, diamorphine, hydromorphone, oxycodone or oxymorphone.

Nausea and Vomiting: Occur frequently after single doses of narcotics or as an early unwanted effect of regular opioid analgesic therapy.

Withdrawal Syndrome: Physical dependence with or without psychological dependence tends to occur with chronic administration. An abstinence syndrome may be precipitated when an opioid analgesic is abruptly discontinued or opioid antagonists are administered. The following withdrawal symptoms may be observed after abrupt discontinuation of an opioid analgesic: body aches, diarrhea, gooseflesh, loss of appetite, nervousness or restlessness, runny nose, sneezing, tremors or shivering, stomach cramps, nausea, sleep disturbances, unusual increase in sweating and yawning, weakness, tachycardia and unexplained fever. With appropriate medical use and gradual withdrawal from opioid analgesics, these symptoms are usually mild.

Other: Abnormal liver function test results (propoxyphen flushing /warmth).

SYMPTOMS AND TREATMENT OF OVERDOSAGE

May result in euphoria, dysphoria visual disturbances, hypotension and coma or death from respiratory depression.

Treatment: Symptomatic and supportive therapy. Maintain ventilation and administer oxygen as needed. The opioid antagonist naloxone should be administered. If the patient is conscious and has not lost the gag reflex, empty the stomach by inducing emesis with ipecac syrup. If the patient is extremely drowsy, unconscious, convulsing or has no gag reflex, perform gastric lavage. Follow with activate charcoal (50 to 100 g in adults) and a cathartic.

For management of a suspected drug overdose, contact your Regional Poison Control Centre immediately.

DOSAGE AND ADMINISTRATION

Codeine 15 and Codeine 30 should not be used in children less than 12 years old.

Codeine, including Codeine 15 and Codeine 30, should be prescribed at the lowest effective dose for the shortest period of time. Dosing should be as needed every 4 to 6 hours and not on scheduled intervals. Dosing and administration should be individualised for each patient taking into account the following:

the nature and severity of pain and medical status of the patient (e.g., renal and hepatic function), daily dose and potency of other opioids or other medication given previously or concurrently, and the degree of tolerance experienced. A thorough assessment of the patient and diagnosis of the pain and its cause should precede the use of potent opioid analgesics for the management of persistent pain.

Adults: Individual dosing requirements vary considerably based on each patient's age, weight, severity and cause of pain, and medical and analgesic history.

15 and 30 mg tablets:

Analgesia: Oral Administration; adults and children 12 years of age or older: 15 to 60 mg every 4 to 6 hours as necessary.

Antitussive: Oral: Adults and children 12 years of age or older: 15 to 30 mg every 6 to 8 hours as necessary to a maximum of 120 mg daily.

Children under 12 years of age: Safety and efficacy of codeine in children has not been established and its use in this age group is not recommended.

Doses should be adjusted in renal failure: for creatinine clearance of 10 to 50 mL/min, decrease the dose by 25% and titrate. If creatinine clearance is less than 10 mL/min, decrease the dose by 50% and titrate.

Supplied:

CODEINE 15: each white tablet contains 15 mg of codeine phosphate. Also contains as non medicinal ingredients: colloidal silicon dioxide, lactose, magnesium stearate, microcrystalline cellulose, and sodium croscarmellose. Available in bottles of 100 tablets.

CODEINE 30: each white tablet contains 30 mg of codeine phosphate. Also contains as non medicinal ingredients: colloidal silicon dioxide, lactose, magnesium stearate, microcrystalline cellulose, and sodium croscarmellose. Available in bottles of 100 and 500 tablets.

Store between 15-30 ^{o}C

PHARMACEUTICAL INFORMATION

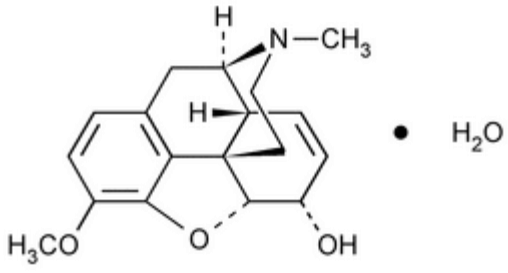
Proper name: **Codeine Phosphate**

Chemical name: Morphinan-6-ol,7,8-didehydro-4,5-epoxy-3-methoxy-17-methyl-, (5α, 6α)-, phosphate (1:1) (salt).

Molecular formula: $C_{18}H_{24}NO_7P$

C54.41%, H6.09%, N3.53%, O28.18%, P7.79%

Structural formula:



Molecular weight: 397.37

Physical state: Hemihydrate, fine, white, needle-shaped crystals; a crystalline powder; odourless, affected by light.

Solubility: Freely soluble in water, very soluble in hot water, slightly soluble in alcohol, more soluble in boiling alcohol.

ANNEX 1 OPIOID ANALGESICS: APPROXIMATE ANALGESIC EQUIVALENCES[4]

Drug Equivalent dose (mg) [5] Duration of Action (compared to morphine 10 mg IM)

Drug	**Equivalent Dose (mg) [5] (compared to morphine 10 mg i.m.)**		**Duration of Action (hours)**
	Parenteral	**Oral**	
Strong Opioid Agonists Morphine Single dose : Chronic dose :	 10 10	 60 20-30 [6]	 3-4 3-4
Hydromorphone	1.5-1	6-7.5	2-4
Anileridine	25	75	2-3
Levorphanol	2	4	4-8
Meperidine[4]	75	300	1-3
Oxymorphone	1.5	5 (rectal)	3-4
Methadone[5]	-	-	-
Heroin	5-8	10-15	3-4
Weak Opioid Agonists Codeine	 120	 200	 3-4
Oxycodone	5-10	10-15	2-4
Propoxyphene	50	100	2-4
Mixed Agonist-Antagonists [6] Pentazocine[4]	 60	 180	 3-4
Nalbuphine	10	-	3-6
Butorphanol	2	-	3-4

REFERENCE

1 Cancer Pain: A monograph on the Management of Cancer Pain, Health and Welfare Canada 1984.

2 Foley, K.M. New Engl. J. Med. 313: 84-95, 1985. Aronoff, G.M. and Evans, W.O., In: Evaluation and Treatment of chronic Pain 2nd Ed., G.M. Aronoff (Ed.), Williams and Wilkins, Baltimore, pp. 359-368 1992.

3 Cheerny, N.I. and Portenoy, R.K., In: Textbook of Pain, 3rd Ed., P.D. Wall and R. Melzack (Eds.), Churchill Livingstone, London, pp. 1437-1467, 1994.

4 Most of these data were derived from single-dose, acute pain studies and should be considered an approximation for selection of doses when treating chronic pain.

5 For acute pain, the oral dose of morphine is six times the injectable dose. However, for chronic dosing, this ration becomes 2 or 3: 1, possibly due to the accumulation of active metabolites.

6 These drugs are not recommended for the management of chronic pain.

7 ratio-CODEINE Prescribing Information, Ratiopharm Inc. Subsimsion Contrl No. 165206 Dated June 26, 2013.

PART III: CONSUMER INFORMATION

ⓃCODEINE 15 and ⓃCODEINE 30
Codeine Phosphate Tablets, USP
15 mg and 30mg

This leaflet is designed specifically for Consumers.
This leaflet is a summary and will not tell you everything about CODEINE 15 and CODEINE 30. Contact your doctor or pharmacist if you have any questions about this drug.

Keep CODEINE 15 and CODEINE 30 in a safe place away from children and pets. Accidental use by a child is a medical emergency and may result in death. Never take medicine in front of small children as they will want to copy you. If a child accidentally takes CODEINE 15 and CODEINE 30, get emergency help right away.

Please read this before you start taking **CODEINE 15 and CODEINE 30** tablets. Remember this information does not take the place of your doctor's instructions.

 Do not attempt to break, chew, dissolve or crush **CODEINE 15 and CODEINE 30** tablets before swallowing.
The CODEINE 30 strength has a score line to facilitate halving, if directed by your doctor. The half tablets should also be swallowed intact.
 CODEINE 15 and CODEINE 30, including halved tablets, must be swallowed whole and should not be altered in any way. If the tablets are altered, codeine could be released too fast. This can lead to serious and life-threatening breathing problems. Life-threatening breathing problems can also happen because of an overdose or if the dose you are using is too high for you.
Get emergency medical help immediately if you:
 have trouble breathing, or have slow or shallow breathing
 have a slow heartbeat
 have severe sleepiness
 have cold, clammy skin
 feel faint, dizzy, confused, or cannot think, walk or talk normally
 have a seizure
 have hallucinations
 Never give **CODEINE 15 and CODEINE 30** to anyone else, even if they have the same symptoms as you have. It may harm them or even cause death.
 Tell your doctor if you (or a family member) have ever abused or been dependent on alcohol, prescription medicines or street drugs.
 Prevent theft, misuse or abuse. Keep **CODEINE 15 and CODEINE 30** in a safe place to protect it from being stolen.
 After you stop taking **CODEINE 15 and CODEINE 30**, you should take the unused tablets to your pharmacist to be destroyed.

What the medication is used for:

CODEINE 15 and CODEINE 30 are used for adults and children 12 years and older to relieve:
 mild to moderate pain
 non-productive cough that does not respond to other cough medicines

Your pain may increase or decrease from time to time and your doctor may need to change the amount of codeine you take daily (daily dosage).

What it does:
CODEINE 15 and CODEINE 30 are indicated for the symptomatic treatment of mild to moderate pain of various causes and the control of exhausting, nonproductive cough which does not respond to non-opioid antitussives.

Codeine belongs to a class of drugs which is commonly referred to as opiates, opioids or narcotics, and also includes fentanyl, hydromorphone, morphine and oxycodone.

When it should not be used:
CODEINE 15 and CODEINE 30 should not be used if
- Your doctor did not prescribe it for you;
- Your pain is mild;
- Your pain can be controlled by occasional use of other painkillers;
- You have severe asthma or severe lung problems;
- You are allergic to codeine or opioids or any other ingredient in the tablets (see What the nonmedicinal ingredients are:);
- You suffer from alcoholism;
- You have a head injury;
- You suffer from seizures;
- You have a condition where the small bowel does not work properly (paralytic ileus) or you have severe pain in your abdomen, or are at risk of blocked intestines;
- You had surgery less than 24 hours ago;
- You are taking, or have taken within the past 2 weeks, a monoamine oxidase inhibitor medication (e.g., phenelzine sulphate, tranylcypromine sulphate, moclobemide, rasagiline or selegiline);
- You are pregnant, or intend to become pregnant;
- You are in labour;
- If you know that you are an ultra-rapidmetabolizer of codeine, you are taking codeine, and you wish to breast-feed: your baby could be harmed.
- Do not use in children less than 12 years old.

Go to a hospital emergency room immediately if you are breastfeeding and your baby is having difficulty breathing or feeding, or is very sleepy or limp.

What the medicinal ingredient is:
Codeine phosphate

What the non-medicinal ingredients are:

Tablets - colloidal silicon dioxide, lactose, magnesium stearate, microcrystalline cellulose, and sodium croscarmellose

What dosage forms it comes in:
Tablet: 15mg and 30 mg

CODEINE 15 and CODEINE 30 are not recommended for anyone who has or is at risk for breathing problems such as:
- Lung infections, or respiratory conditions
- Neuromuscular disorders
- Severe heart problems
- Recent multiple traumas or extensive surgical procedures

CODEINE 15 and CODEINE 30 tablets must be swallowed whole and should not be chewed, dissolved or crushed, since this can cause the release of too much codeine that can seriously harm you. The CODEINE 30 strength has a score line to facilitate halving, if directed by your doctor. The half tablets should also be swallowed intact.

You should not consume alcohol while taking CODEINE 15 and CODEINE 30, as it may increase the chance of experiencing dangerous side effects.

Keep CODEINE 15 and CODEINE 30 out of sight and reach of children. You should not give CODEINE 15 and CODEINE 30 to anyone as inappropriate use may have severe medical consequences, including death.

Your doctor should know about all of your medical conditions before deciding if **CODEINE 15 and CODEINE 30** is right for you and what daily dosage is best.

Tell your doctor about all of your medical problems, especially the following ones:
- difficulty breathing,
- asthma or other chronic lung problems;
- head injury or brain tumor;
- liver or kidney problems;
- gastrointestinal problems;
- low blood pressure;
- prostate problems;
- difficulty in urinating;
- adrenal gland problems, such as Addison's disease;
- convulsions or seizures;
- alcoholism;
- hallucinations or other severe mental problems;
- past or present substance abuse or drug addiction
- you know that you are an ultra-rapid metabolizer of codeine.

Consult your doctor before use if you are taking tranquilizers, sedatives, sedating antihistamines, or other depressants, or products containing acetylsalicylic acid, caffeine, codeine or muscle relaxants, or 3 or more alcoholic beverages per day.

Driving, operating hazardous machinery, or other tasks requiring full alertness should not be attempted for the first few days of taking **CODEINE 15 and CODEINE 30**, or after your daily dosage is changed, since you may experience drowsiness or sedation. If drowsiness or sedation occurs, do not undertake such activities until you have talked with your doctor.

IN

You should not take **CODEINE 15 and CODEINE 30** if you are currently taking (or recently stopped taking) one of the medicines known as monoamine oxidase inhibitors (e.g. phenelzine sulphate, tranylcypromine sulphate, moclobemide, rasagiline or selegiline).

Tell your doctor about all medicines that you are taking. Your doctor should decide whether you can take **CODEINE 15 and CODEINE 30** with other medicines. These include:
• Naltrexone
• other opioids, pain medicines, muscle relaxants, anaesthetics, sedatives, tranquilizers, antidepressants, hypnotics, barbiturates, phenothiazines, amphetamines, chlorpromazine, methocarbamol, some heart medications (e.g., beta-blockers), blood-thinners (coumarin or other anticoagulants), chloral hydrate and glutethimide (not available in Canada);
• sedating antihistamines for allergy, cough and cold medicines, depressants, alcoholic beverages or sleep aids (these medicines could depress your breathing or your level of consciousness); medicines that you buy yourself without a prescription; • any herbal remedies that you may be taking.

This list may not describe all possible interactions. Give your health care provider a list of all the medicines, herbs, non-prescription drugs, or dietary supplements you use. Also tell them if you smoke, drink alcohol, or use illegal drugs. Some items may interact with your medicine.

CODEINE 15 and CODEINE 30 tablets must be swallowed whole and should not be chewed, dissolved or crushed, since this can cause the release of too much

codeine that can seriously harm you. The CODEINE 30 strength has a score line to facilitate halving, if directed by your doctor. The half tablets should also be swallowed intact.

CODEINE 15 and CODEINE 30 are not recommended for rectal administration.

Usual dose:
Adults and children 12 years of age or older:

For Pain:
15 to 60 mg every 4 to 6 hours if necessary.

For Cough:
15 to 30 mg every 6 to 8 hours if necessary to a maximum of 120 mg daily.

Your doctor should prescribe **CODEINE 15 and CODEINE 30** at the lowest effective dose for the shortest period of time. **Take CODEINE 15 and CODEINE 30 every 4-6 hours as needed.** A new written prescription is required from your doctor each time you need more **CODEINE 15 and CODEINE 30**. Therefore, it is important that you contact your doctor at least three working days before your current supply runs out. Do not seek additional prescriptions for **CODEINE 15 and CODEINE 30** from any other doctor – unless responsibility for your pain/cough management has been transferred to another doctor.

Consult your doctor if you feel sedated or drowsy, confused, have shallow breathing, or have severe constipation. Should your pain/cough increase or any other complaint develop as a result of taking **CODEINE 15 and CODEINE 30**, tell your doctor immediately.

Review your pain/cough regularly with your doctor to determine if you still need **CODEINE 15 and CODEINE 30**. Be sure to use **CODEINE 15 and CODEINE 30** only for the condition for which it was prescribed.

Overdose:
The most important signs of overdose are suppressed breathing (abnormally slow or weak breathing), dizziness, confusion, or extreme drowsiness. Other symptoms are euphoria, dysphoria, pinpoint pupils, visual disturbances and cold or clammy skin.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms. Take you medicine with you.

Missed Dose:

It is very important that you do not miss any doses. If you miss one dose, take it as soon as possible, but if it is almost time for your next dose, then skip the missed dose. Do not take two doses at once, unless your doctor tells you to. If you miss several doses in succession, talk to your doctor before restarting.

Do not seek additional prescriptions for this medicine from any other doctor – unless responsibility for your pain management has been transferred to another doctor.

Should your pain increase or any other complaint develop as a result of taking **CODEINE 15 and CODEINE 30**, tell your doctor immediately.

The most common side effects you may experience are constipation, nausea, drowsiness, dizziness, vomiting, headache, dry mouth, weakness and sweating. Tell your doctor about these problems if they arise. Your doctor may prescribe a laxative and/or stool softener to help relieve constipation while you are taking **CODEINE 15 and CODEINE 30**.

Consult your doctor if you feel sedated or drowsy, confused, or have severe constipation. If you experience any symptoms related to difficulty in breathing, such as tight chest or wheezing, or shallow breathing, fainting, or rapid heartbeat, go to a hospital emergency room immediately.

If you are a nursing mother taking codeine, call your doctor if you become extremely sleepy and have trouble caring for your baby.

Breastfed babies usually nurse every two to three hours and should not sleep more than four hours at a time. If your baby shows signs of more than usual sleepiness, difficulty breastfeeding, breathing difficulties, or limpness, take the baby immediately to a hospital emergency room.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		**Talk with your doctor or pharmacist right away**		**Stop taking drug and seek immediate emergency medical attention**
		Only if severe	**In all cases**	
Very Common	Consipation	√		
	Nausea	√		
	Drowsiness	√		

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist right away		Stop taking drug and seek immediate emergency medical attention
		Only if severe	In all cases	
Common	Dizziness	√		
	Vomiting	√		
	Itching	√		
	Headache	√		
	Dry mouth	√		
	Weakness	√		
	Sweating	√		
Uncommon	Difficulty in breathing, such as tight chest or wheezing, fainting or rapid or slow heartbeat or shallow breathing.			√
	Swelling of the face, lips, or tongue.			√
	Confusion			√
	Trouble passing urine or change in the amount of urine.			√

This is not a complete list of side effects. For any unexpected effects while taking CODEINE, contact your doctor or pharmacist.

Store **CODEINE 15 and CODEINE 30** in a secure place to prevent theft and misuse. Keep out of sight and reach of children.

Store at room temperature 15- 30ºC.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

-1. Report online at www.healthcanada.gc.ca/medeffect

2. Call toll-free at 1-866-234-2345

3. Complete a Canada Vigilance Reporting Form and:

- Fax toll-free to 1-866-678-6789, or
- Mail to: Canada Vigilance Program
  Health Canada
  Postal Locator 0701E
  Ottawa, Ontario
  K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at

www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

This document plus the full product monograph, prepared for health professionals can be found by contacting Laboratoires Trianon Inc.at:
1-800-363-7988

This leaflet was prepared by:
Laboratoires Trianon Inc
660 boul Industriel
Blainville, Québec
Canada, J7C 3V4

Last revised: October 11, 2013.