PRODUCT MONOGRAPH

INCLUDING PATIENT MEDICATION INFORMATION

[N]ROBITUSSIN® AC

Guaifenesin, Codeine Phosphate and Pheniramine Maleate Syrup
100 mg/10 mg/7.5 mg: per 5 mL of syrup

Expectorant/Cough Suppressant/Antihistamine

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Date of Review:
November 28, 2016

Submission Control No: 195638

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ROBITUSSIN® AC

Guaifenesin, Codeine Phosphate and Pheniramine Maleate Syrup

PART I: HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form / Strength	Nonmedicinal Ingredients
Oral	Syrup, each 5 mL of which contains: guaifenesin 100 mg, codeine phosphate 10 mg and pheniramine maleate 7.5 mg	Alcohol, caramel colour, citric acid, FD&C Red No. 40, FD&C Yellow No. 6, glycerin, invert sugar, menthol flavour, purified water, raspberry flavours and sodium benzoate

INDICATIONS AND CLINICAL USE

Adults
Robitussin® AC is indicated for temporary expectoration and control cough associated with inflamed mucosa.

Geriatrics (> 65 years of age)
In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, concomitant disease or other drug therapy (see **ACTION AND CLINICAL PHARMACOLOGY**, **Special Populations and Conditions**, **Geriatrics**).

Pediatrics (< 18 years of age)
The safety and efficacy of Robitussin® AC has not been studied in the pediatric population. Therefore the use of Robitussin® AC is not recommended in patients under 12 years of age.

CONTRAINDICATIONS

- Patients who are hypersensitive to the active substance codeine, guaifenesin, pheniramine or other opioid analgesics or to any ingredient in the formulation. For a complete listing, see the **DOSAGE FORMS, COMPOSITION AND PACKAGING** section of the Product Monograph.

- In patients with known or suspected mechanical gastrointestinal obstruction (e.g., bowel obstruction or strictures) or any diseases/conditions that affect bowel transit (e.g., ileus of any type).
- Patients with acute or severe bronchial asthma, chronic obstructive airway, or 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).

WARNINGS AND PRECAUTIONS

SERIOUS WARNINGS AND PRECAUTIONS

Risks From Concomitant Use With Benzodiazepines Or Other CNS Depressants
Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death (see WARNINGS AND PRECAUTIONS). Avoid use of opioid cough medications in patients taking benzodiazepines, other CNS depressants, or alcohol.

General

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 physiological complications, and that appropriate therapy for the primary disease is provided.

Accidental ingestion, especially by children can result in a fatal overdose of codeine (see DOSAGE AND ADMINISTRATION, disposal, for instructions on proper disposal).

Patients should be cautioned not to consume alcohol while taking Robitussin® AC as it may increase the chance of experiencing serious adverse events, including death. Stop use and consult a doctor if symptoms or cough worsen or persist for more than 7 days or if high fever, rash or persistent headache is present, as these may be signs of a serious condition.

Abuse and Misuse

Like all opioids, **Robitussin® AC** is a potential drug of abuse and misuse, which can lead to overdose and death. Therefore, **Robitussin® AC** should be prescribed and handled with caution.

Opioids, such as **Robitussin® AC**, should be used with particular care in patients with a history of alcohol and illicit/prescription drug abuse.

Cardiovascular
Codeine administration may result in hypotension and dizziness. Use with caution in patients with cardiac arrhythmias due to the cholinergic effects of the drug.

Dependence/Tolerance
As with other opioids, tolerance and physical dependence may develop upon repeated administration of Robitussin® AC and there is a potential for development of psychological dependence.

Physical dependence and tolerance reflect the neuroadaptation of the opioid receptors to chronic exposure to an opioid, and are separate and distinct from abuse and addiction. Tolerance, as well as physical dependence, may develop upon repeated administration of opioids, and are not by themselves evidence of an addictive disorder or abuse.

Gastrointestinal Effects

Codeine and other morphine-like opioids have been shown to decrease bowel motility. Codeine may obscure the diagnosis or clinical course of 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.

Neonatal Opioid Withdrawal Syndrome (NOWS)
Use of Robitussin® AC is contraindicated in pregnant women (see **CONTRAINDICATIONS**).

Prolonged maternal use of opioids during pregnancy can result in withdrawal signs in the neonate. Neonatal opioid withdrawal syndrome, unlike opioid withdrawal syndrome in adults, may be life-threatening.

Neonatal opioid withdrawal syndrome presents as irritability, hyperactivity and abnormal sleep pattern, high pitched cry, tremor, vomiting, diarrhea and failure to gain weight. The onset, duration, and severity of neonatal opioid withdrawal syndrome vary based on the specific opioid used, duration of use, timing and amount of last maternal use, and rate of elimination of the drug by the newborn.

Neurologic

Interactions with Central Nervous System Depressants (including benzodiazepines and alcohol): Concomitant use of opioids, including Robitussin® AC, with benzodiazepines, or other CNS depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Because of these risks, avoid use of opioid cough medications in patients taking benzodiazepines, other CNS depressants, or alcohol (see **DRUG INTERACTIONS**).

Observational studies have demonstrated that concomitant use of opioid analgesics and benzodiazepines increases the risk of drug-related mortality compared to use of opioids alone. Because of similar pharmacologic properties, it is reasonable to expect similar risk with concomitant use of opioid cough medications and benzodiazepines, other CNS depressants, or alcohol.

Advise both patients and caregivers about the risks of respiratory depression and sedation if Robitussin® AC is used with benzodiazepines, alcohol, or other CNS depressants.

Head Injury: The respiratory depressant effects of codeine, and the capacity to elevate cerebrospinal fluid pressure, may be greatly increased in the presence of an already elevated intracranial pressure produced by trauma. Also, codeine may produce confusion, miosis, vomiting and other side effects which obscure the clinical course of patients with head injury. In such patients, codeine must be used with extreme caution and only if it is judged essential (see **CONTRAINDICATIONS).**

Peri-Operative Considerations

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.

Psychomotor Impairment

Robitussin® AC may impair the mental and/or physical abilities needed for certain potentially hazardous activities such as driving a car or operating machinery. Patients should be cautioned accordingly. Patients should also be cautioned about the combined effects of Codeine with other CNS depressants, including other opioids, phenothiazine, sedative/hypnotics and alcohol.

Respiratory

Codeine, including Robitussin® AC 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.

Life-threatening respiratory depression is more likely to occur in the elderly, cachectic, or debilitated patients because they may have altered pharmacokinetics or altered clearance compared to younger, healthier patients.

Use in Patients with Chronic Pulmonary Disease: Monitor patients with significant chronic obstructive pulmonary disease or cor pulmonale, and patients having a substantially decreased respiratory reserve, hypoxia, hypercapnia, or pre-existing respiratory depression for respiratory

depression, particularly when initiating therapy and titrating with Robitussin® AC, as in these patients, even usual therapeutic doses of Robitussin® AC may decrease respiratory drive to the point of apnea. The use of Robitussin® AC > is contraindicated in patients with acute or severe bronchial asthma, chronic obstructive airway, or status asthmaticus (see **CONTRAINDICATIONS**).

Special Populations

Special Risk Groups: Codeine should be administered with caution to patients with a history of alcohol and drug abuse and in a reduced dosage to debilitated patients, and in patients with severely impaired pulmonary function, Addison's disease, hypothyroidism, glaucoma, myxedema, toxic psychosis, prostatic hypertrophy or urethral stricture.

Pregnant Women:

Pregnant Women: Studies in humans have not been conducted. Robitussin® AC crosses the placental barrier and should not be administered to pregnant women unless in the judgment of the physician, potential benefits outweigh the risks.

Prolonged maternal use of opioids during pregnancy can result in withdrawal signs in the neonate. Neonatal Opioid Withdrawal Syndrome (NOWS), unlike opioid withdrawal syndrome in adults, can be life-threatening (see **WARNINGS AND PRECAUTIONS, Neonatal Opioid Withdrawal Syndrome, ADVERSE REACTIONS, Post-marketing Experience**).

Labour, Delivery and Nursing Women: Since opioids can cross the placental barrier and are excreted in breast milk, Robitussin® AC should not be used unless, in the judgement of the physician, the potential benefits outweigh the risks. Respiratory depression can occur in the infant if opioids are administered during labour. Naloxone, a drug that counters the effects of opiates, should be readily available.

Pediatrics (< 18 years of age): Robitussin® AC may cause drowsiness or excitability, especially in children. Robitussin® AC is not recommended for children under 12 years of age.

Geriatrics (> 65 years of age): In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range and titrate slowly, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy (see **DOSAGE AND ADMINISTRATION** and **ACTION AND CLINICAL PHARMACOLOGY**, **Special Populations and Conditions**, **Geriatrics**).

Ultra-rapid Metabolizers of Codeine

Some individuals may be ultra-rapid metabolizers due to a specific CYP2D6*2×2 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 and shallow breathing.

Use in 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 infants are rare. However, some women are ultra-rapid metabolizers of codeine (see **WARNINGS AND PRECAUTIONS, Ultra-rapid Metabolizers of Codeine**). These women achieve higher-than expected levels of morphine in breastmilk 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 CYPD2D6 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 Americans, 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 mother and baby. Caution should be excercised 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.

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

ADVERSE REACTIONS

Adverse Drug Reaction Overview

Adverse reactions due to codeine phosphate may include drowsiness, nausea, vomiting and constipation. Infrequent adverse effects include palpitation, dry mouth, skin rash, pruritus and, rarely, hyperhidrosis and agitation have been reported. Respiratory depression is seen in higher dosage, and there is a potential for tolerance, psychological dependence or physical dependence to occur.

Post-marketing Experience

Spontaneously Reported Adverse Events for ^{N}ROBITUSSIN® AC (guaifenesin, codeine phosphate and pheniramine maleate)

Since the inception of marketing **^{N}ROBITUSSIN® AC,** (combination product Guaifenesin, Codeine Phosphate and Pheniramine Maleate**)** Pfizer has received 5 cases describing 8 adverse events. The following events were reported singly; Condition aggravated, Cough, Drug hypersensitivity, Drug ineffective, Insomnia and Overdose, while Somnolence was reported twice.

DRUG INTERACTIONS

Overview

Interaction with Benzodiazepines and Other Central Nervous System (CNS) Depressants (including alcohol): Due to additive pharmacologic effect, the concomitant use of benzodiazepines or other CNS depressants (e.g. other opioids, sedatives/hypnotics, antidepressants, anxiolytics, tranquilizers, muscle relaxants, general anesthetics, antipsychotics, phenothiazines, neuroleptics, antihistamines, antiemetics, and alcohol) and beta-blockers, increases the risk of respiratory depression, profound sedation, coma, and death and should be avoided (see **WARNINGS AND PRECAUTIONS, Neurologic, Interactions with Central Nervous System Depressants (including benzodiazepines and alcohol) and Psychomotor Impairment**). Robitussin® AC should not be consumed with alcohol as it may increase the chance of experiencing dangerous side effects.

Drug-Lifestyle Interactions
The concomitant use of alcohol should be avoided (see **WARNINGS AND PRECAUTIONS, General**).

DOSAGE AND ADMINISTRATION

Dosing Considerations
Robitussin® AC may be taken with or without food, with a glass of water.

Recommended Dose and Dosage Adjustment
Codeine, including Robitussin AC, 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.

Adults:
Take 10 mL (2 tsps) every 4 to 6 hours as follows or as directed by a doctor. Do not exceed 6 doses (12 tsp.) in a 24-hour period.

Geriatrics:
Respiratory depression has occurred in the elderly following administration of large initial doses of opioids to patients who were not opioid-tolerant or when opioids were co-administered with

other agents that can depress respiration. Robitussin® AC should be initiated at a low dose and slowly titrated to effect (see **WARNINGS AND PRECAUTIONS** and **ACTION AND CLINICAL PHARMACOLOGY**).

Disposal

Robitussin® AC should be kept in a safe place, out of the sight and reach of children before, during and after use. Robitussin® AC should not be used in front of children, since they may copy these actions.

Robitussin® AC should never be disposed of in household trash. Disposal via a pharmacy take back program is recommended. Unused or expired Robitussin® AC should be properly disposed of as soon as it is no longer needed to prevent accidental exposure to others, including children or pets.

Missed Dose

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take your medicine and skip the missed dose. Do not take two doses at the same time.

OVERDOSAGE

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

Symptoms: 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 narcotic 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 activated charcoal (50 to 100 g in adults) and a cathartic.

ACTION AND CLINICAL PHARMACOLOGY

Mechanism of Action

Codeine Phosphate: Codeine is a narcotic analgesic which binds to the mu receptor as an opiate receptor agonist. Although the exact mechanism of analgesic action is unknown, it may come from its conversion to morphine. Codeine is also associated with antitussive effects via direct depression of the medullary cough reflex.

Pheniramine Maleate: Pheniramine is an alkylamine derivative which is a potent H1 antagonist. Its actions are mediated by reversible and competitive inhibition of the interaction of histamine with H1 receptors on cells, preventing histamine effects on target organs.

Guaifenesin: Guaifenesin is thought to act as an expectorant by increasing the volume and reducing the viscosity of secretions in the trachea and bronchi. Thus, it may increase the efficiency of the cough reflex and facilitate removal of the secretions. However, objective

evidence for this is limited and conflicting

STORAGE AND STABILITY

Robitussin® AC should be stored at room temperature (15-30°C).

Others:
Keep in a safe place out of the reach of children.

DOSAGE FORMS, COMPOSITION AND PACKAGING

Composition:
Each 5 mL of orange, cherry-flavored syrup contains: guaifenesin 100 mg, codeine phosphate 10 mg and pheniramine maleate 7.5 mg.

Nonmedicinal ingredients: alcohol, caramel colour, citric acid, FD&C Red No. 40, FD&C Yellow No. 6, glycerin, invert sugar, menthol flavour, purified water, raspberry flavours and sodium benzoate.

Energy: 13.9 kcal /5 mL. Sodium: 0.8 mg/5mL. Gluten-, parabens- and tartrazine (FD&C Yellow No. 5)-free.

Packaging:
Bottles of 1 L.

PART II: SCIENTIFIC INFORMATION

PHARMACEUTICAL INFORMATION

Drug Substance

Proper name:
Guaifenesin
Codeine Phosphate
Pheniramine Maleate

Chemical name:
Guaifenesin:

IUPAC Name: (*RS*)-3-(2-methoxyphenoxy)propane-1,2-diol
CAS Name: 3-(2-Methoxyphenoxy)-1,2-propanediol
Additional Names: glycerol mono(2-methoxyphenyl) ether; glycerol α-(2-methoxyphenyl) ether; guaiacyl glyceryl ether; glyceryl guaiacyl ether; glycerol guaiacolate; α-glyceryl guaiacol ether; *o*-methoxyphenyl glyceryl ether; 1,2-dihydroxy-3-(2-methoxyphenoxy)propane; guaiacol glyceryl ether; guaiphenesin; guaiacuran

Codeine:

IUPAC Name: (4R,4aR,7S,7aR,12bS)-9-methoxy-3-methyl-2,4,4a,7,7a,13-hexahydro-1H-4,12-methanobenzofuro[3,2-e]isoquinoline-7-ol
CAS Name: (5α,6α)-7,8-Didehydro-4,5-epoxy-3-methoxy-17-methylmorphinan-6-ol
Additional Names: methylmorphine; morphine monomethyl ether; morphine 3-methyl ether

Pheniramine Maleate:

IUPAC Name: (Z)-but-2-enedioic acid;N,N-dimethyl-3-phenyl-3-pyridin-2-ylpropan-1-amine

Molecular formula and molecular mass:
Guaifenesin:

Molecular Formula: $C_{10}H_{14}O_4$

Molecular Weight: 198.22

Codeine:

Molecular Formula: $C_{18}H_{21}NO_3$

Molecular Weight: 299.36

Codeine Phosphate:

Molecular Formula: $C_{18}H_{21}NO_3 \cdot H_3PO_4$

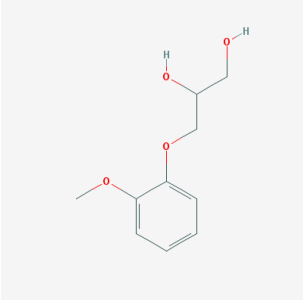
Molecular Weight: 397.36

Pheniramine Maleate:

Molecular Formula: $C_{16}H_{20}N_2 \cdot C_4H_4O_4$

Molecular Weight: 356.42

Structural formula:
Guaifenesin:



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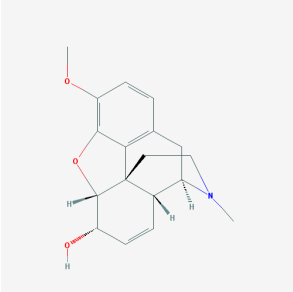

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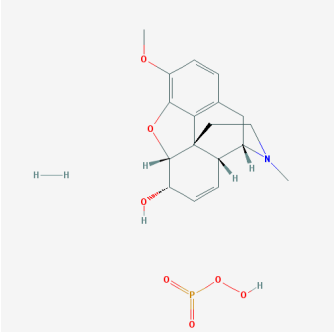

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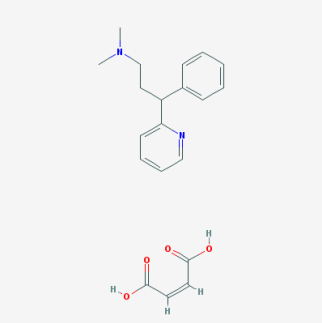

Physicochemical Properties:
Guaifenesin: Crystals, melting point 132-134 °C. Freely soluble in water; soluble in alcohol, chloroform. pH of a 2% aqueous solution about 5. Slightly soluble in ether, benzene.

Codeine Phosphate: Fine, white, needle-shaped crystals or crystalline powder. Odorless; affected by light. Solutions acidic to litmus. Freely soluble in water; very soluble in hot water; slightly soluble in alcohol; more soluble in boiling alcohol.

Pheniramine Maleate: Crystals from amyl alcohol, faint amine-like odor, melting point 107 °C. Soluble in water, alcohol; slightly soluble in ether, benzene. pH of 1% aqueous solution between 4.3 and 4.9.

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

ROBITUSSIN® AC

Guaifenesin, Codeine Phosphate and Pheniramine Maleate Syrup

Read this carefully before you start taking **Robitussin® AC** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Robitussin® AC**.

Serious Warnings and Precautions

Taking Robitussin® AC with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.

What is Robitussin® AC used for?

Robitussin® AC is used for the temporary relief of dry coughs, chest congestion, runny nose and sneezing associated with*:*

- the common cold

How does Robitussin® AC work?

Codeine Phosphate acts on the brain to supress cough.
Guaifenesin helps relieve chest congestion.
Pheniramine Maleate helps relieve runny nose and sneezing.

What are the ingredients in Robitussin® AC?

Medicinal ingredients: Guaifenesin, Codeine Phosphate and Pheniramine Maleate

Non-medicinal ingredients: Alcohol, caramel colour, citric acid, FD&C Red No. 40, FD&C Yellow No. 6, glycerin, invert sugar, menthol flavour, purified water, raspberry flavour and sodium benzoate

Robitussin® AC comes in the following dosage forms:

Syrup, each 5 mL of which contains: guaifenesin 100 mg, codeine phosphate 10 mg and pheniramine maleate 7.5 mg

Do not use Robitussin® AC if you:

- are allergic to guaifenesin, codeine phosphate and pheniramine maleate or to any of the other ingredients in Robitussin® AC
- feel sedated, drowsy or confused

- have severe asthma, trouble breathing, or other breathing problems
- have bowel blockage or narrowing of the stomach or intestines
- have a head injury
- are at risk for having seizures
- suffer from alcoholism
- are taking or have taken within the past 2 weeks a Monoamine Oxidase inhibitor (MAOi) (such as phenelzine sulphate, tranylcypromine sulphate, moclobemide or selegiline)

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Robitussin® AC. Talk about any health conditions or problems you may have, including if you:

- have a history of illicit or prescription drug or alcohol abuse
- have severe kidney disease
- have severe liver disease
- have low blood pressure
- have or had depression
- suffer from chronic or severe constipation
- have persistent or chronic cough (as occurs with smoking), glaucoma, high blood pressure, heart disease
- have problems with your thyroid, adrenal or prostate gland
- have, or had in the past hallucinations or other severe mental problems
- or under a physician's care
- are pregnant or planning to become pregnant
- are breastfeeding

Other warnings you should know about:

Accidentally taking Robitussin® AC can result in a fatal overdose. This is especially true if a child accidently takes it.

As with all opioids, taking guaifenesin, codeine phosphate and pheniramine maleate may cause you to become dependent on it. Do not take more than the dose prescribed to you by your doctor.

If you took Robitussin® AC while you were pregnant, whether for short or long periods of time or in small or large doses, your baby can suffer life-threatening withdrawal symptoms after birth. This can occur in the days after birth and for up to 4 weeks after delivery. If your baby has any of the following symptoms:

- **has changes in their breathing (such as weak, difficult or fast breathing)**
- **is unusually difficult to comfort**
- **has tremors (shakiness)**
- **has increased stools, sneezing, yawning, vomiting, or fever**

Seek immediate medical help for your baby.

Driving and using machines: Before you do tasks which may require special attention, you should wait until you know how you react to Robitussin® AC. Robitussin® AC can cause:

- drowsiness
- dizziness or
- lightheadedness

This can usually occur after you take your first dose and when your dose is increased.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Robitussin® AC:

- Alcohol. This includes prescription and non-prescription medications that contain alcohol. **Do not** drink alcohol while you are taking Robitussin® AC. It can lead to:
    - drowsiness
    - unusually slow or weak breathing
    - serious side effects or
    - a fatal overdose
- opioid analgesics (drugs used to treat pain)
- general anesthetics (drugs used during surgery)
- benzodiazepines (drugs used to help you sleep or that help reduce anxiety)
- antidepressants (for depression and mood disorders). **Do not** take Robitussin® AC with MAO inhibitors (MAOi) or if you have taken MAOi's in the last 14 days.
- drugs used to treat serious mental or emotional disorders (such as schizophrenia)
- antihistamines (drugs to treat allergies)
- antitussives
- decongestants
- expectorants
- anti-emetics (drugs used to prevent vomiting)
- drugs used to treat muscle spasms and back pain
- warfarin (such as coumadin) and other anticoagulants (used to prevent or treat blood clots)
- anti-retroviral drugs (used to treat viral infections)
- anti-fungal drugs (used to treat fungal infections)
- antibiotic drugs (used to treat bacterial infections)
- some heart medication (such as beta blockers)
- grapefruit juice

How to take Robitussin® AC:

Usual Dose:

Take every 4–6 hours or as directed by a physician. Maximum 6 doses daily.
Adults (12 years & over): 2 teaspoons (10 mL)
Children under 12 years: **DO NOT USE**

Overdose:

If you think you have taken too much Robitussin® AC, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Signs of overdose may include:

- unusually slow or weak breathing
- dizziness
- confusion
- extreme drowsiness

Missed Dose:
Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take your medicine and skip the missed dose. Do not take two doses at the same time.

What are possible side effects from using Robitussin® AC?
These are not all the possible side effects you may feel when taking Robitussin® AC. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- Drowsiness
- Insomnia
- Dizziness
- Fainting
- Nausea, vomiting, or a poor appetite
- Dry mouth
- Headache
- Problems with vision
- Weakness, uncoordinated muscle movement
- Itching
- Sweating
- Constipation

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
RARE **Overdose:** hallucinations,			T

confusion, inability to walk normally, slow or weak breathing, extreme sleepiness, sedation, or dizziness, floppy muscles/low muscle tone cold and clammy skin.			
Respiratory Depression: Slow, shallow or weak breathing.			T
Allergic Reaction: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			T
Bowel Blockage (impaction): abdominal pain, severe constipation, nausea			T
Fast, Slow or Irregular Heartbeat: heart palpitations.		T	
Low Blood Pressure: dizziness, fainting, light-headedness.	T		

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects
We encourage you to report serious or unexpected side effects to Health Canada. The information is used to check for new safety concerns about health products. As a consumer, your report contributes to the safe use of health products for everyone.
3 ways to report:

- Online at MedEffect;
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
  - Fax to 1-866-678-6789 (toll-free), or
  - Mail to: Canada Vigilance Program
    Health Canada, Postal Locator 0701E
    Ottawa, ON
    K1A 0K9

  Postage paid labels and the Consumer Side Effect Reporting Form are available at 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.

Storage:

Store at room temperature (15°-30°C). **Keep unused or expired Robitussin® AC in a secure place to prevent theft, misuse or accidental exposure to children and pets.**

Keep Robitussin® AC out of sight and reach of children and pets.

Disposal:

Robitussin® AC should never be thrown into household trash, where children and pets may find it. It should be returned to a pharmacy for proper disposal.

If you want more information about Robitussin® AC:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this consumer medication information by visiting the Health Canada website; or by calling the sponsor, Pfizer Consumer Healthcare, a division of Pfizer Canada Inc., Mississauga, Ontario L5R 4B2 at 1-888-275-9938.

This leaflet was prepared by Pfizer Consumer Healthcare, a division of Pfizer Canada Inc.

Last Revised November 28, 2016