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## Guaifenesin

(gwe fen' e sin)


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### IMPORTANT WARNING:

#### FDA Intends to Remove *Some* Unapproved Cough, Cold, and Allergy Drugs from the Market

*This safety alert does not apply to this medication, but only to some products which contain this medication. In addition, it is important that you know that there is not a problem with most of the products described in this medication monograph. And some drug companies may decide to seek full approval from the FDA so that they can continue marketing their products.*

On March 2, 2011, the Food and Drug Administration (FDA) issued a safety alert about certain unapproved prescription cough, cold, and allergy products containing this drug in combination with other drugs. These products are not currently approved by the FDA for safety, effectiveness, and quality. FDA asked drug companies to stop shipping most of these products for sale in the US within the next 6 months. Although some of these products have been marketed for many years, laws about what a company must prove to FDA for drug product approval have gotten tougher and increased enforcement of these laws is now taking place. The FDA took this action due to concerns about certain potential risks associated with use of these medications. These risks may include:

- the possibility of improper use in infants and young children
- potentially risky combinations of ingredients
- patients receiving too much or too little of the medication because of problems with the way some "timed-release" products are made

If you are concerned that the prescription cough, cold, and allergy medication you are taking is not approved by the FDA, you should talk to your doctor or pharmacist. If the medication you are taking is not approved, your doctor can prescribe another prescription medication or your doctor or pharmacist can suggest an over-the-counter (OTC) cough, cold, and allergy product for your condition. There are many safe and effective alternative approved products that can be taken instead. Your doctor probably prescribed the medicine without knowing that FDA had not approved it. This is because it has been so difficult for doctors and pharmacists to find out that these products are unapproved. For additional information:

- You can visit the FDA website (<http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm244852.htm>) for more information about this action to remove unapproved cough, cold, and allergy products from the market.
- You can find a list of unapproved products by going to (<http://goo.gl/Gqc7d>).
- For information on how to dispose of unused products, go to <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm101653.htm>.

### Why is this medication prescribed?

Guaifenesin is used to relieve chest congestion. Guaifenesin may help control symptoms but does not treat the cause of symptoms or speed recovery.

Guaifenesin is in a class of medications called expectorants. It works by thinning the mucus in the air passages to make it easier to cough up the mucus and clear the airways.

### How should this medicine be used?

Guaifenesin comes as a tablet, a capsule, an extended-release (long-acting) tablet, dissolving granules, and a syrup (liquid) to take by mouth. The tablets, capsules, dissolving granules, and syrup are usually taken with or without food every 4 hours as needed. The extended-release tablet is usually taken with or without food every 12 hours. Follow the directions on the package or on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take guaifenesin exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Guaifenesin comes alone and in combination with antihistamines, cough suppressants, and decongestants. Ask your doctor or pharmacist for advice on which product is best for your symptoms. Check nonprescription cough and cold product labels carefully before using two or more products at the same time. These products may contain the same active ingredient(s) and taking them together could cause you to receive an overdose. This is especially important if you will be giving cough and cold medications to a child.

Nonprescription cough and cold combination products, including products that contain guaifenesin, can cause serious side effects or death in young children. Do not give these products to children younger than 4 years of age. If you give these products to children 4 to 11 years of age, use caution and follow the package directions carefully.

If you are giving guaifenesin or a combination product that contains guaifenesin to a child, read the package label carefully to be sure that it is the right product for a child of that age. Do not give guaifenesin products that are made for adults to children.

Before you give a guaifenesin product to a child, check the package label to find out how much medication the child should receive. Give the dose that matches the child's age on the chart. Ask the child's doctor if you don't know how much medication to give the child.

If you are taking the liquid, do not use a household spoon to measure your dose. Use the measuring spoon or cup that came with the medication or use a spoon made especially for measuring medication.

Swallow the extended-release tablets whole with a full glass of water. Do not break, crush, or chew them.

If you are taking the dissolving granules, empty the entire contents of the packet onto your tongue and swallow.

If your symptoms do not improve within 7 days or if you also have a high fever, a rash, or a headache that does not go away, call your doctor.

### Other uses for this medicine [Return to top](#)

This medication is sometimes prescribed for other uses; ask your doctor or pharmacist for more information.

### What special precautions should I follow? [Return to top](#)

Before taking guaifenesin,

- tell your doctor and pharmacist if you are allergic to guaifenesin, any other medications, or any of the ingredients in the guaifenesin product you plan to take. Check the package label for a list of the ingredients.
- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take.
- tell your doctor if you smoke and if you have or have ever had a cough that occurs with a large amount of phlegm (mucus) or if you have or have ever had a breathing problem such as asthma, emphysema, or chronic bronchitis. If you will be taking the dissolving granules, tell your doctor if you are on a low magnesium diet or if you have kidney disease.
- tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. If you become pregnant while taking guaifenesin, call your doctor.
- if you have phenylketonuria (PKU, a inherited condition in which a special diet must be followed to prevent mental retardation), you should know that the dissolving granules may be sweetened with aspartame, a source of phenylalanine.

### What special dietary instructions should I follow? [Return to top](#)

Drink plenty of fluids while you are taking this medication.

Unless your doctor tells you otherwise, continue your normal diet.

### What should I do if I forget a dose? [Return to top](#)

Guaifenesin is usually taken as needed. If your doctor has told you to take guaifenesin regularly, take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

### What side effects can this medication cause? [Return to top](#)

Guaifenesin may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- headache
- nausea
- vomiting

Guaifenesin may cause other side effects. Call your doctor if you have any unusual problems while you are taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online [at <http://www.fda.gov/Safety/MedWatch>] or by phone [1-800-332-1088].

### What should I know about storage and disposal of this medication? [Return to top](#)

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom). Throw away any medication that is outdated or no longer needed. Talk to your pharmacist about the proper disposal of your medication.

### In case of emergency/overdose [Return to top](#)

In case of overdose, call your local poison control center at 1-800-222-1222. If the victim has collapsed or is not breathing, call local emergency services at 911.

### What other information should I know? [Return to top](#)

Ask your pharmacist any questions you have about guaifenesin.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

### Brand names [Return to top](#)

- Adult Tussin<sup>®</sup>
- Air Power<sup>®</sup>
- Bronchoril<sup>®</sup>
- Chest Congestion<sup>®</sup>
- Childrens Mucinex<sup>®</sup>
- Childrens Mucus Relief<sup>®</sup>
- Cough Out<sup>®</sup>
- Diabetic Siltussin DAS-Na<sup>®</sup>
- Diabetic Tussin Expectorant<sup>®</sup>
- Diabetic Tussin Mucus Relief<sup>®</sup>
- Equaline Tussin<sup>®</sup>
- Equate Tussin<sup>®</sup>
- Good Neighbor Pharmacy Tussin<sup>®</sup>
- Good Sense Tussin<sup>®</sup>
- Guiatuss<sup>®</sup>
- Iophen NR<sup>®</sup>
- Kids-EEZE<sup>®</sup>
- Leader Adult Tussin<sup>®</sup>
- Leader Mucus Relief<sup>®</sup>
- Liqufruta<sup>®</sup>
- Little Remedies Little Colds Mucus Relief Expectorant Melt Aways<sup>®</sup>
- MucaPlex<sup>®</sup>
- Mucinex<sup>®</sup>
- Mucinex for Kids<sup>®</sup>
- Mucus Relief<sup>®</sup>
- Mucus Relief Chest<sup>®</sup>
- ORGAN-I NR<sup>®</sup>
- Premier Value Chest Congestion Relief<sup>®</sup>
- Q-Tussin<sup>®</sup>
- Refenesen<sup>®</sup> Chest Congestion Relief
- Robitussin<sup>®</sup> Chest Congestion
- Scot-Tussin<sup>®</sup> Expectorant SF Cough
- SelectHealth Tussin DM<sup>®</sup>
- Siltussin DAS<sup>®</sup>
- Siltussin SA<sup>®</sup>
- Smart Sense Tussin<sup>®</sup>
- Sunmark Tussin<sup>®</sup>
- Topcare Mucus Relief<sup>®</sup>
- Topcare Tussin<sup>®</sup>
- Tussin<sup>®</sup>
- Tussin Chest<sup>®</sup>
- Tussin Chest Congestion<sup>®</sup>
- Tussin Original<sup>®</sup>
- Up and Up Childrens Mucus Relief<sup>®</sup>
- Vicks<sup>®</sup> DayQuil<sup>®</sup>
- Wal Tussin<sup>®</sup>

### Brand names of combination products [Return to top](#)

- Adult Tussin DM<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Aldex<sup>®</sup> (containing Guaifenesin, Pseudoephedrine)
- Biocotron<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Biospec<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Bisolvine<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Care One Chest Congestion Relief<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Certuss<sup>®</sup> (containing Chlophedianol, Guaifenesin)
- Cheratussin AC<sup>®</sup> (containing Codeine, Guaifenesin)
- chest congestion<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Childrens Mucus Relief<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Childrens Mucus Relief Cherry<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Childrens Mucus Relief Cough Cherry<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Childrens Relief Cherry<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Chlo Tuss<sup>®</sup> (containing Chlophedianol, Guaifenesin)
- Healthy Accents Tussin DM<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Iophen C NR<sup>®</sup> (containing Codeine, Guaifenesin)
- Iophen DM NR<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Leader Adult Tussin DM<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Leader Childrens Mucus Relief Cough<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Leader Intense Cough Reliever<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Leader Tussin DM Max<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Lusair<sup>®</sup> (containing Guaifenesin, Phenylephrine)
- Mucinex Fast-Max<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Mucus Relief Cough<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Mucus Relief DM<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Nature Fusion<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- PediaCare Childrens Cough and Congestion<sup>®</sup> (containing Dextromethorphan, Guaifenesin)

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- Codar (containing Codeine, Guaifenesin)
- Cough<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Cough Syrup<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- CounterAct<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- CVS Chest Congestion Relief<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Dex-Tuss<sup>®</sup> (containing Codeine, Guaifenesin)
- DG Health Childrens Mucus Relief Cough<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- DG Health Tussin DM<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Diabetic Tussin DM<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Diabetic Tussin DM Maximum Strength<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Donatussin Drops<sup>®</sup> (containing Guaifenesin, Phenylephrine)
- Double Tussin Intense Cough Reliever<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Equaline Adult Tussin<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Equaline Tussin Cough and Chest Congestion<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Equate Tussin DM<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Expectorant Plus Cough Relief<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- FormuCare Cough Syrup DM<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Freds Chest Congestion Relief<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Good Neighbor Pharmacy Adult Tussin<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Good Neighbor Pharmacy Tussin DM<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Good Neighbor Pharmacy Tussin DM Max<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Good Sense Childrens Mucus Relief Cough<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Good Sense tussin<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Good Sense Tussin DM<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Guaiasorb DM<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Guaiatussin AC<sup>®</sup> (containing Codeine, Guaifenesin)
- Guiatuss DM<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Premier Value Chest Congestion and Cough Relief (containing Dextromethorphan, Guaifenesin)
- Primatene<sup>®</sup> (containing Ephedrine, Guaifenesin)
- Q Tussin DM<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- RelCof-C<sup>®</sup> (containing Codeine, Guaifenesin)
- Robafen DM Max<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Robitussin Cough and Chest Congestion DM<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Safetussin<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Scot-Tussin Senior SF DME<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Smart Sense Mucus Relief Cough<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Smart Sense tussin dm max<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Sun Mark Mucus Relief Cough<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Sun Mark Tussin DM<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Sunmark Tussin DM<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Topcare Mucus Relief<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Topcare tussin dm<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Topcare Tussin DM Max<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Tussin Cough DM<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Tussin DM<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Up and Up Adult Cough Formula DM<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Up and Up Childrens Mucus Relief and Cough<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Vanacof<sup>®</sup> (containing Chlophedianol, Guaifenesin)
- Vicks<sup>®</sup> DayQuil<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Wal Tussin DM<sup>®</sup> (containing Dextromethorphan, Guaifenesin)
- Z-Cof 1<sup>®</sup> (containing dextromethorphan and Guaifenesin, Pseudoephedrine)
- Zicam<sup>®</sup> (containing acetaminophen and Dextromethorphan, Guaifenesin)
- Zodyl DEC<sup>®</sup> (containing pseudoephedrine and Codeine, Guaifenesin)
- Zyncof<sup>®</sup> (containing Dextromethorphan, Guaifenesin)

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