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ESPAÑOL

Chlorpheniramine



(klor fen ir' a meen)

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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?

Chlorpheniramine relieves red, itchy, watery eyes; sneezing; itchy nose or throat; and runny nose caused by allergies, hay fever, and the common cold. Chlorpheniramine helps control the symptoms of cold or allergies but will not treat the cause of the symptoms or speed recovery. Chlorpheniramine is in a class of medications called antihistamines. It works by blocking the action of histamine, a substance in the body that causes allergic symptoms.

How should this medicine be used?

Chlorpheniramine comes as a tablet, a capsule, an extended-release (long-acting) tablet and capsule, a chewable tablet, and a liquid to take by mouth. The regular capsules and tablets, chewable tablets, and liquid are usually taken every 4 to 6 hours as needed. The extended-release (long-acting) tablets and capsules are usually taken twice a day in the morning and evening as needed. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take chlorpheniramine exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Chlorpheniramine comes alone and in combination with fever and pain reducers, expectorants, 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 2 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 chlorpheniramine, 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 4-11 years of age, use caution and follow the package directions carefully.

If you are giving chlorpheniramine or a combination product that contains chlorpheniramine 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 chlorpheniramine products that are made for adults to children.

Before you give a chlorpheniramine 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.

If you are using the extended-release tablets or capsules, swallow them whole. Do not break, crush, chew, or open them.

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 chlorpheniramine,

- tell your doctor and pharmacist if you are allergic to chlorpheniramine, any other medications, or any of the ingredients in the chlorpheniramine product you plan to use. 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. Be sure to mention any of the following: other medications for colds, hay fever, or allergies; medications for anxiety, depression, or seizures; muscle relaxants; narcotic medications for pain; sedatives; sleeping pills; and tranquilizers.
- tell your doctor if you have or have ever had asthma, emphysema, chronic bronchitis, or other types of lung disease; glaucoma (a condition in which increased pressure in the eye can lead to gradual loss of vision); ulcers; diabetes; difficulty urinating (due to an enlarged prostate gland); heart disease; high blood pressure; seizures; or an overactive thyroid gland.
- tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. If you become pregnant while taking chlorpheniramine, call your doctor.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking chlorpheniramine.
- you should know that this medication may make you drowsy. Do not drive a car or operate machinery until you know how this medication affects you.
- ask your doctor about the safe use of alcohol while you are taking chlorpheniramine. Alcohol can make the side effects of chlorpheniramine worse.

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

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

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

Chlorpheniramine is usually taken as needed. If your doctor has told you to take chlorpheniramine 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](#)

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

- drowsiness
- dry mouth, nose, and throat
- nausea
- vomiting

- loss of appetite
- constipation
- headache
- increased chest congestion

Some side effects can be serious. If you experience any of the following symptoms, call your doctor immediately:

- vision problems
- difficulty urinating

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.

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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.

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Ask your pharmacist any questions you have about chlorpheniramine.

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](#)

- Antagonate[®][¶]
- Chlor-Trimeton[®]
- Efidac 24[®][¶]
- Kloromin[®][¶]
- Phenetron[®][¶]
- Pyridamal 100[®][¶]
- Teldrin[®][¶]

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

- Advil[®] Allergy and Congestion Relief (containing Chlorpheniramine, Ibuprofen, Phenylephrine)
- Advil[®] Allergy Sinus (containing Chlorpheniramine, Ibuprofen, Phenylephrine)
- Children's[®] Advil Allergy Sinus (containing Chlorpheniramine, Ibuprofen, Phenylephrine)
- Codimal-L.A. 12[®] (containing Chlorpheniramine, Pseudoephedrine)[¶]
- Isoclor[®] (containing Chlorpheniramine, Pseudoephedrine)[¶]
- Codeprex[®] (containing Chlorpheniramine, Codeine)[¶]
- Penntuss[®] (containing Chlorpheniramine, Codeine)[¶]
- Tussicaps[®] (containing Chlorpheniramine, Hydrocodone)
- Tussionex Pennkinetic[®] (containing Chlorpheniramine, Hydrocodone)
- Vituz[®] (containing Chlorpheniramine, Hydrocodone)
- Zutripro[®] (containing Chlorpheniramine, Hydrocodone, Pseudoephedrine)

[¶] This branded product is no longer on the market. Generic alternatives may be available.

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