

DOXYLAMINE

What is in this leaflet

The medicine you have purchased contains doxylamine.

This leaflet is intended to provide information on the active ingredient doxylamine, which is contained in many different medicines. The packaging of the medicine you have bought should be read carefully. This leaflet provides additional information on doxylamine which should also be read and understood.

Please read this leaflet and the packaging of the medicine you have purchased carefully before you start using doxylamine.

This leaflet answers some common questions about doxylamine. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What doxylamine is used for

Doxylamine belongs to a group of medicines called 'sedating antihistamines' which help reduce allergic symptoms by preventing the effects of a substance called histamine. Histamine is produced by the body in response to foreign substances that the body is allergic to. It also works directly on the brain to help you feel more relaxed.

Sedating antihistamines are used in different situations:

- to relieve red, itchy, watery eyes; sneezing; itchy nose or throat; and runny nose caused by the common cold, as well as allergies and hay fever.
- to stop you feeling sick or being sick, such as travel sickness.
- to help control anxiety or help you go to sleep.
- to relieve some of the symptoms of the common cold.

The age of people who can use medicines containing doxylamine varies depending on the reason for use. Read the medicine packaging carefully and talk to your pharmacist or doctor.

There may be more than one active ingredient in your medicine, such as paracetamol, ibuprofen, a nasal decongestant or a cough suppressant. If you are taking more than one cough and cold medicine, please read the packaging of each medicine carefully to ensure you are not taking the same active ingredient from 2 or more medicines. Taking the same active ingredient from more than one medicine could mean you are taking too much of that active ingredient.

Ask your doctor or pharmacist if you have any questions about doxylamine.

Before you use doxylamine

When you must not use it

Do not use doxylamine:

- if you have asthma.
- if you have chronic bronchitis.
- if you have severe liver or kidney disease.
- if you have unusual heart beats.
- if you are a man with prostate problems.
- if you have difficulty passing urine.
- if you have glaucoma (increased pressure in the eye).
- if you have a narrowing or blockage between the stomach and small intestine which causes vomiting of undigested food.
- if you have epilepsy.
- if you are pregnant or breastfeeding.
- in a child under 12 years of age.
- if you are taking a medicine known as a monoamine oxidase inhibitor (MAOI) or have taken one in the last 14 days.
- if you are taking tricyclic antidepressants, medicines to help you relax or sleep (sedatives) or strong pain killers.
- if you are allergic to doxylamine or any of the other ingredients listed on the back of the medicine packaging.

Some of the symptoms of an allergic reaction may include:

- shortness of breath.
- wheezing or difficulty breathing.
- swelling of the face, lips, tongue or other parts of the body.
- rash, itching or hives on the skin.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using doxylamine, talk to your doctor or pharmacist.

Before you start to use it

Tell your doctor or pharmacist if:

- You have allergies to any other medicines, foods, preservatives or dyes.
- You are taking medicines to help you relax or sleep (sedatives).
- You have or have had any of the following medical conditions:
 - liver or kidney disease.
 - breathing problems.
 - heart disease.
 - high blood pressure.

Tell your doctor or pharmacist if you are pregnant or plan to become pregnant.

Your doctor or pharmacist will discuss the benefits and possible risks of taking doxylamine during pregnancy.

Ask your doctor or pharmacist about taking doxylamine if you are breastfeeding.

It is not known if doxylamine passes into the breast milk. Your doctor or pharmacist will discuss the potential benefits and risks of taking doxylamine if you are breastfeeding.

Do not use doxylamine in children under 12 years of age.

If you have not told your pharmacist or doctor about any of the above, tell him/her before you start taking doxylamine.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicine, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Tell your doctor or pharmacist if you are taking any other cough and cold medicines.

You should also tell any health professional who is prescribing a new medication for you that you are taking doxylamine.

Some medicines and doxylamine may interfere with each other.

You must not take doxylamine if you are taking:

- monoamine oxidase inhibitor medicines (used for depression and Parkinson's disease) or have taken them within the last 14 days. These include moclobemide, phenelzine, and tranylcypromine.
- tricyclic antidepressant medicines such as amitriptyline (Tryptanol) imipramine (Melipramine), nortriptyline (Allegron) and doxepin (Deptran).
- medicines used to help you sleep or relax (sedatives and hypnotics).
- strong pain killers, such as codeine, morphine and dextropropoxyphene.

Talk to your pharmacist or doctor before you take doxylamine if you are using any of the following:

- any heart medicines (especially digoxin).

- drugs for helping blood circulation and controlling angina (such as glyceryl trinitrate) or beta-blockers (e.g. atenolol).
- antibiotics.
- epilepsy treatments.
- medicines used to stop blood clotting, such as warfarin.
- other cough and cold medicines.

These medicines may be affected by doxylamine or may affect how well it works. You may need different amounts of your medicine or you may need to take different medicines.

Your doctor or pharmacist will have more information on medicines to be careful with or avoid while taking doxylamine.

How to use doxylamine

Follow any directions given to you by your pharmacist or doctor carefully. They may differ from the information contained in this leaflet.

Read the packaging and this leaflet carefully before taking doxylamine. If you do not understand the instructions on the packaging, ask your pharmacist for help.

How much to take

Follow the instructions on the packaging of the product you have purchased. You may also wish to discuss how much to take and when to take it with your pharmacist or doctor.

Doses of doxylamine are usually taken 4 – 6 hourly as required, with a maximum of 4 doses in any 24 hour period.

Do not take more than the amount recommended on the packaging of the medicine you have purchased.

Doxylamine may or may not be taken with food.

Doxylamine is usually contained in the night-time medicine. Follow the instructions on the packaging for its use in conjunction with the day-time medicine.

Do not give to children under 12 years of age.

If the symptoms persist for more than a few days, or worsen, consult your doctor or pharmacist.

If you forget to take it

Take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your pharmacist or doctor.

While you are using doxylamine

Things you must do

Talk to your pharmacist or doctor if your symptoms do not improve.

Your pharmacist or doctor will assess your condition and decide if you should continue to take the medicine.

If you are about to be started on any new medicine tell your doctor or pharmacist that you are taking doxylamine.

Things you must not do

Do not give doxylamine to anyone else, even if they have the same condition as you.

Do not take doxylamine to treat any other complaints unless your pharmacist or doctor tells you to.

Do not take more than the recommended dose unless your doctor tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how doxylamine affects you.

Doxylamine may cause dizziness in some people. If this happens, do not drive or operate machinery.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much doxylamine.

Do this even if there are no signs of discomfort or poisoning. You may need medical attention.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using doxylamine.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects. Talk to your doctor or pharmacist if you have any questions or concerns.

If you experience any of the following stop using the medicine and seek immediate medical help:

- difficulty in breathing, swelling of the face, neck, tongue or throat (these are signs of a severe allergic reaction).
- fast, pounding or irregular heartbeats.

If you experience any of the following symptoms, or have any other unusual symptoms or concerns with your medicine, stop taking it and talk to your pharmacist or doctor:

- fast heart rate, changes in heart rhythm, irregular heart beats, palpitations (feeling your Heartbeat), high blood pressure.
- feeling sick, vomiting.
- wheezing or being short of breath.
- men may have difficulty passing urine.
- constipation.
- tremors.
- nervousness, restlessness, excitation.
- fainting.
- blurred vision.
- increased gastric reflux.
- skin rash, pinkish, itchy swellings on the skin.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

After using doxylamine

Storage

Keep your medicine in the original pack until it is time to take it.

Do not use after the expiry date shown on the carton of your medicine.

Do not store above the temperature shown on the packaging of your medicine

Store in the original container.

Keep it out of sight and where children cannot reach it.

Disposal

Ask your pharmacist what to do with any medicine that is left over, or if the expiry date has passed.

Product description

The active ingredient is: doxylamine succinate

The other ingredients: including other active ingredients are listed on the packaging of the product you have bought or on the leaflet inside the pack.

Doxylamine is available in a number of medicines used to treat coughs, colds and influenza. It is usually contained in tablets, capsules, or caplets. Always read the packaging of the medicine you have purchased carefully to see which ingredients it contains.

Date of Preparation

This leaflet was prepared on 30 September 2010.

This leaflet was prepared under the guidance of the New Zealand Self-Medication Industry (NZSMI):

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Should you have any questions regarding the product you have purchased, please contact your doctor, pharmacist or the manufacturer (contact details should be provided on the packaging of the medicine you have purchased).