

[Medicine name][®] *(If you want to include phonetic spelling, the Second Edition of the Usability Guidelines suggests using the system outlined in the Webster's International Dictionary).*

Generic name

The following substances are covered by this core CMI:

- Chlorpheniramine maleate
- Dexchlorpheniramine maleate
- Diphenhydramine hydrochloride
- Doxylamine succinate
- Promethazine hydrochloride
- Triprolidine hydrochloride

Consumer Medicine Information

Date of Dispensing

This Core leaflet covers both prescription and non-prescription products containing antihistamines, and therefore must be modified to suit the particular product being written about. Information in the CMI must be consistent with the product's Product Information (PI).

When writing about consumers seeking advice from health professionals, the schedule of the product should be taken into consideration. Thus:

- S4 products should direct consumers to seek advice from their **doctor or pharmacist**, and
- S3 products should direct consumers to seek advice from their **pharmacist or doctor**.

What is in this leaflet

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

All medicines have risks and benefits. Your pharmacist or doctor has weighed the risks of you taking [Medicine name] against the benefits they expect it will have for you.

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

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

What [Medicine name] is used for

[Substance name] is used to (*insert indication as specified in the ARTG, or for a non-validated grandfathered product, as specified on the product label*).

- *List multiple indications in dot points*

[Substance name] belongs to a group of medicines called 'antihistamines'. Antihistamines 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.

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

Your pharmacist or doctor may have given it for another reason.

Below are further statements that may be included in this section.

It is only available from your pharmacist.

This medicine is only available on a prescription from your doctor.

Before you take/give [Medicine name]

When you must not take it

Do not take [Medicine name] if you have an allergy to:

- any medicine containing [substance name] or other antihistamines
- any of the ingredients listed at the end of this leaflet.

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 if you have or have had any of the following medical conditions:

- glaucoma (high pressure in the eyes)
- stomach or duodenal ulcer, or other stomach problems
- prostate problems
- bladder problems

Do not take [substance name] if you are also taking monoamine oxidase inhibitors, a type of medicine used to treat depression.

Do not take promethazine if you are pregnant or plan to become pregnant. (*for promethazine-containing products*)

It may affect your developing baby if you take it during pregnancy. Your pharmacist or doctor will discuss the benefits and possible risks of taking the medicine during pregnancy.

Do not take [substance name] if you are breastfeeding or plan to breastfeed.

It passes into the breast milk and there is a possibility that the baby may be affected.

Do not give [substance name] to newborn or premature babies.

Do not give promethazine to infants under 12 months of age. (*for promethazine-containing products*)

Do not take this medicine/it 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 taking this medicine, talk to your pharmacist or doctor (or doctor or pharmacist).

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- kidney or liver disease
- epilepsy

Tell your pharmacist or doctor if you take sedatives.

Tell your pharmacist or doctor if you are pregnant or plan to become pregnant (*do not use this statement for promethazine, which is contraindicated in pregnancy*).

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

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

Taking other medicines

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

Some medicines and [Medicine name] may interfere with each other.

These include:

- medicines used to treat depression, especially monoamine oxidase inhibitors and tricyclic antidepressants
- medicines used to help you sleep or relax (sedatives and hypnotics)
- opioid analgesics, medicines used to treat pain
- phenytoin, a medicine used to treat epilepsy (*for chlorpheniramine-containing products only*)

These medicines may be affected by [Medicine name] or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

How to take [Medicine name]

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

If you do not understand the instructions on the box/bottle, ask your pharmacist or doctor for help.

How much to take

Include dosage ranges, usual doses for each indication or patient group etc .as specified on the product label.

Do not take more than the recommended dose.

If you are over 65 years of age, talk to you pharmacist or doctor about how much to take.

Elderly patients are more likely to have side effects from taking these medicines.

How to take it

Include specific instructions as specified on the product label.

When to take it

Include specific instructions as specified on the product label.

How long to take it

Include specific instructions as specified on the product label.

If you forget to take it

Following are examples of statements that may be included in this section.

If it is less than ‘x’ hours before your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, 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.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (in Australia, call 13 11 26; in New Zealand, call 0800 764 766) for advice or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much [Medicine name]. Do this even if there are no signs of discomfort or poisoning.

While you are using [Medicine name]

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.

Things you must not do

Do not drink alcohol while taking [substance name].

The sedation effects of alcohol may be increased.

Do not take [Medicine name] to treat any other complaints unless your pharmacist or doctor tells you to.

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

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

Things to be careful of

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

This medicine may cause sleepiness in some people. If this happens, do not drive or use operate machinery.

Side effects

Tell your pharmacist or doctor as soon as possible if you do not feel well while you are taking [Medicine name].

This medicine helps most people with (*indication*), but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your pharmacist or doctor to answer any questions you may have.

Tell your pharmacist or doctor if you notice any of the following and they worry you:

- drowsiness or sleepiness
- dry mouth, nose and throat
- constipation
- nervousness and irritability
- anxiety
- hallucinations
- twitching or jerking muscles
- fast heart beat

The above list includes the more common side effects of your medicine. They are usually mild.

Tell your doctor as soon as possible if you notice any of the following:

- difficult or painful urination
- seizures (fits)

The above list includes serious side effects that may require medical attention. These side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- skin rashes

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your pharmacist or doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using [Medicine name]

Storage

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

Keep your medicine in a cool dry place where the temperature stays below x°C.

Do not store [Medicine name] or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

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

Product description

What it looks like

Include identifying details as appropriate, such as dose form, colour and markings of tablets, colour and consistency of liquids, pack sizes, etc.

Ingredients

[Medicine name] contains x mg of (*generic name*) as the active ingredient.

It also contains:

- *list excipients in dot points*
- Where Australian Food Standard codes exist, these could follow each Australian Approved name.*

As appropriate, the CMI may include a negative list of ingredients. For example: This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Manufacturer/Distributor/Supplier

(use appropriate heading)

[Medicine name] is made/distributed/supplied in Australia by:

Include name and address of sponsor

® = Registered Trademark *or*

™ = Trademark (*if appropriate*)

This leaflet was prepared in *month/year*.

Include AUST R number(s)

You may want to include a document code and/or a reference to the approved PI.