

BENADRYL[®] Original Oral Liquid

(New Formula)

Diphenhydramine hydrochloride, Ammonium chloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about BENADRYL Original Oral Liquid. 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 BENADRYL Original 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 BENADRYL Original is used for

BENADRYL Original is used to relieve the symptoms of dry raspy coughs due to a cold.

BENADRYL Original contains medicines called diphenhydramine and ammonium chloride.

Diphenhydramine belongs to a group of medicines called 'antihistamines'. Diphenhydramine helps to reduce common cold symptoms, such as runny nose, sneezing and watery eyes. Diphenhydramine also helps suppress dry, raspy coughs by its action in the brain. Ammonium chloride is an expectorant.

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

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

Before you take BENADRYL Original

When you must not take it

Do not take BENADRYL Original if you have an allergy to:

- any medicine containing diphenhydramine or other antihistamines
- any medicine containing ammonium chloride
- 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 are also taking monoamine oxidase inhibitors, a type of medicine used to treat depression.

Do not take this medicine if you have had any of the following medical conditions:

- narrow-angle glaucoma

- duodenal or stomach ulcers or other stomach problems
- prostate problems
- bladder problems
- severe liver failure
- severe renal impairment

Do not give this medicine to babies or children under six years of age.

Do not take this medicine after the expiry date (EXP) 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.

Before you start to take it

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

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

- breathing problems such as emphysema or chronic bronchitis
- chronic obstructive airways disease
- pneumonia
- asthma
- persistent or chronic coughs or coughs that produce a lot of mucus
- kidney or liver disease
- epilepsy

- glaucoma.

Ask your pharmacist or doctor before using in children 6 years and over.

Do not use this medicine if you are having an asthma attack.

Do not take with other sedating antihistamines.

Tell your pharmacist or doctor if you take sedatives.

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

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

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

Your pharmacist or doctor will discuss the benefits and possible risks of taking the medicine if you are breastfeeding.

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

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 BENADRYL Original may interfere with each other.

These include:

- medicines used to treat depression such as monoamine oxidase inhibitors (especially if taken within the last 14 days) and tricyclic antidepressants
- medicines used to help you relax, sleep or relieve anxiety, such as tranquillizers, sedatives and hypnotics
- medicines with strong anticholinergic effects such as some travel sickness medicines,

medicines to relieve stomach cramps or spasms, and medicines used in Parkinson's disease

- opioid analgesics used to treat pain
- alcohol
- betablockers (metoprolol), medicines used to treat high blood pressure, heart conditions and prevent migraines.

These medicines may be affected by BENADRYL Original 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 BENADRYL Original

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

The recommended doses of BENADRYL Original are:

- 6 to 12 years: 5 mL
- Over 12 years: 10 mL

Do not use BENADRYL Original for children under 6 years.

Ask your pharmacist or doctor before using in children 6 years and over.

Do not take more than the recommended dose.

If you are over 65 years of age, talk to your 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

Measure the recommended dose in a medicine measure and swallow.

When to take it

Take the recommended dose every 4 hours, as required.

Do not exceed 6 doses in 24 hours.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, you may take a dose as soon as you remember if you think you need it.

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.

Your next dose should be taken in 4 hours if you think you need it.

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (in Australia, call 13 11 26) 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 BENADRYL Original. Do this even if there are no signs of discomfort or poisoning.

While you are using BENADRYL Original

Things you must do

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

worsen, or if new symptoms appear.

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 BENADRYL Original.

The sedative effects of alcohol may be increased.

Do not take BENADRYL Original 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 dizziness or drowsiness in some people. Drowsiness may continue the following day. If this happens, do not drive or operate machinery.

Side effects

Tell your pharmacist or doctor as soon as possible if you do not feel well while you are taking BENADRYL Original.

This medicine helps most people with dry coughs and cold symptoms, 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
- fatigue
- weakness
- dizziness
- nausea, vomiting or stomach discomfort
- constipation
- diarrhoea
- increased appetite
- thicker phlegm
- dry mouth, nose or throat or eyes.

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:

- blurred vision
- sensitivity to light
- ringing in the ears
- headache
- fast heart beat
- palpitations
- low blood pressure
- tightness of chest or throat
- tingling or numbness of the hands and feet
- difficulty in passing urine
- confusion
- excitation
- insomnia
- nervousness, anxiety or irritability
- restlessness, agitation
- impaired performance (such as with work or driving)
- psychosis (a mental disorder)
- hallucinations
- muscle spasms
- movement disorders, lack of coordination

- tremor
- seizures (fits)
- hives

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:

- severe nausea and vomiting
- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- skin rashes or itching.

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 BENADRYL Original

Storage

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

Keep your medicine in a cool dry place where the temperature stays below 30°C.

Do not store BENADRYL Original 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 your medicine 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.

BENADRYL is a registered trademark.

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Product description

This leaflet was prepared in September 2015.

What it looks like

BENADRYL Original is a clear or slightly opalescent dark red liquid with raspberry flavour. It is available in bottles of 100mL and 200mL.

Ingredients

Each 5 mL of BENADRYL Original contains 12.5 mg of diphenhydramine hydrochloride and 125 mg of ammonium chloride as the active ingredients.

It also contains the following inactive ingredients:

- sucrose
- glucose-liquid
- glycerol
- sodium citrate
- raspberry flavour
- citric acid monohydrate
- saccharin sodium
- menthol
- Allura Red FC
- Brilliant Blue FCF
- sodium benzoate

This medicine contains 135.2mg/40mL (maximum daily dose) of sodium.

This medicine does not contain lactose, gluten or tartrazine.

Sponsor

BENADRYL Original is made in Australia from local and imported components, and sponsored by:

Johnson & Johnson Pacific
45 Jones Street
Ultimo NSW 2007
Australia