BENADRYL Original

Active ingredient(s): Diphenhydramine hydrochloride and Ammonium chloride

Consumer Medicine Information (CMI)

This leaflet provides important information about using BENADRYL Original. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using BENADRYL Original.

Where to find information in this leaflet:

- 1. Why am I using BENADRYL Original?
- 2. What should I know before I use BENADRYL Original?
- 3. What if I am taking other medicines?
- 4. How do I use BENADRYL Original?
- 5. What should I know while using BENADRYL Original?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using BENADRYL Original?

BENADRYL Original contains the active ingredients Diphenhydramine hydrochloride and Ammonium

chloride. Diphenhydramine hydrochloride belongs to a group of medicines called antihistamines. It works by reducing common cold symptoms, such as runny nose, sneezing and watery eyes. It also helps suppress

BENADRYL® Original

dry, raspy coughs by its action in the brain. Ammonium chloride is an expectorant.

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

2. What should I know before I use BENADRYL Original?

Warnings

Do not use BENADRYL Original if:

 you are allergic to Diphenhydramine hydrochloride or other antihistamines, Ammonium chloride, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

Some of the symptoms of an allergic reaction may include shortness or breath, wheezing or difficulty breathing, swelling of the face, lips tongue or other parts of the body, rash, itching or hives on the skin

- you are younger than 6 years
- you are having an asthma attack
- have narrow-angle glaucoma
- have duodenal or stomach ulcers or other stomach problems
- have prostate problems
- have bladder problems
- have severe liver failure

- have severe renal impairment
- have taken other products containing sedating antihistamines.

Check with your doctor or pharmacist:

- before using in children 6 years and over
- if you have any other 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
 - liver or kidney disease
 - epilepsy
 - glaucoma.
- if you take sedatives
- if you take any medicines for any other condition
- if you have allergies to any other medicines, foods, preservatives or dyes.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6. Are there any side effects</u>?

Pregnancy and breastfeeding

Check with your doctor or pharmacist if you are pregnant or intend to become pregnant.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

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

3. What if I am taking other medicines?

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

Some medicines may interfere with BENADRYL Original and affect how it works.

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 (metroprolol), medicines used to treat high blood pressure, heart conditions and prevent migraines.

You may need different amounts of your medicines, or you may need to take different medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect BENADRYL Original.

4. How do I use BENADRYL Original?

How much to take

- The recommended dose of BENADRYL Original for children 6 years to 12 years is 5mL every 4 hours as necessary. The recommended dose for adults and children over 12 years is every 4 hours as necessary
- Follow the instructions provided with the medicine.
- Do not exceed 6 doses in 24 hours.
- Do not exceed the recommended dosage.
- If you are over 65 years of age, talk to your pharmacist or doctor about how much to take.

When to take **BENADRYL** Original

BENADRYL Original should be used every 4 hours as necessary.

How to take **BENADRYL** Original

- Measure the recommended dose in a medicine measure and swallow.
- Follow all directions given to you by your pharmacist or doctor carefully. This may differ from the information contained in this leaflet.
- If you forget to take it and 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.
- If you do not understand the instructions on the pack, ask your pharmacist or doctor for help.

If you use too much BENADRYL Original

If you think that you have used too much BENADRYL Original, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using BENADRYL Original?

Things you should do

Stop use an talk to your doctor or pharmacist if your symptoms persist, worsen, or if new symptoms occur. Your doctor or pharmacist will assess your condition and decide if you should continue to take the medicine.

Remind any doctor, dentist or pharmacist you visit that you are using BENADRYL Original.

Things you should not do

- 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how BENADRYL Original affects you.

BENADRYL Original may cause dizziness in some people .

If this happens, do not drive or operate machinery.

Drinking alcohol

Tell your doctor or pharmacist if you drink alcohol.

Do not take alcohol while using BENADRYL Original. The sedative effects of alcohol may be increased.

Looking after your medicine

- 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.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions.

Less serious side effects	What to do
 fatigue drowsiness weakness dizziness dizziness nausea, vomiting or stomach discomfort constipation diarrhoea increased appetite thicker phlegm dry mouth, nose, throat or eyes 	Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.

Less serious side effects

Serious side effects

Serious side effects	What to do
 blurred vision sensitivity to light ringing in the ears headache fast heart beat palpitations low blood pressure tightness of chest or	Call your doctor straight
throat tingling or numbness of	away, or go straight
the hands and feet difficulty in passing urine confusion excitation insomnia nervousness, anxiety or	to the Emergency
irritability impaired performance	Department at your
(such as with work or	nearest hospital if you
driving) psychosis (a mental	notice any of these
disorder) hallucinations muscle spams	serious side effects.

Serious side effects	What to do
 movement disorders, lack of coordination 	
• tremor	
 seizures (fits) 	
• hives	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people. Children and people over 65 years if age may have an increased chance of getting side effects.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at <u>www.tga.gov.au/reporting-problems</u>. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is available over-the-counter without a doctor's prescription.

What **BENADRYL** Original contains

Active ingredient (main ingredient)	Diphenhydramine hydrochloride Ammonium chloride
Other ingredients	Sucrose
(inactive ingredients)	Glucose-liquid
	Glycerol
	Sodium citrate
	Raspberry flavour
	Citric acid monohydrate
	Saccharin sodium
	Menthol
	Allura Red FC
	Brilliant Blue FCF
	Sodium benzoate

Do not take this medicine if you are allergic to any of these ingredients.

What **BENADRYL** Original looks like

BENADRYL Original is a clear slightly opalescent dark red liquid with raspberry flavour. (Aust R 199371).

Who distributes **BENADRYL** Original

Johnson & Johnson Pacific

45 Jones Street

Ultimo NSW 2007

Australia

Phone: 1800 029979

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