

DEMAZIN Cough Cold & Flu tablets

Pseudoephedrine hydrochloride, paracetamol and dextromethorphan hydrobromide

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DEMAZIN Cough Cold & Flu tablets.

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 DEMAZIN Cough Cold & Flu against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What DEMAZIN Cough Cold & Flu is used for

DEMAZIN Cough Cold & Flu provides temporary relief from:

- nagging cough
- runny noses
- blocked noses and sinus
- sinus pain
- fever
- headache
- body aches and pains

DEMAZIN Cough Cold & Flu contains a combination of three medicines: pseudoephedrine hydrochloride, dextromethorphan and paracetamol.

Pseudoephedrine hydrochloride belongs to a group of medicines called sympathomimetic decongestants.

It works by reducing congestion in the upper respiratory tract, including the nose, nasal passages and sinuses, and making it easier to breathe.

Dextromethorphan is a cough suppressant that acts on the cough centre in the brain to suppress a dry cough.

Paracetamol works to stop the pain messages from getting through to the brain. It also acts in the brain to reduce fever.

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/give DEMAZIN Cough Cold & Flu

When you must not take it

Do not take DEMAZIN Cough Cold & Flu tablets if you have an allergy to:

- any medicine containing pseudoephedrine, paracetamol or dextromethorphan hydrobromide
- 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 having an asthma attack.

Do not take this medicine if you have:

- very high blood pressure
- severe coronary artery disease (heart disease caused by poor blood flow or narrowing of the blood vessels of the heart)
- glaucoma (high pressure in the eyes)
- prostate problems
- bladder problems

Do not take this medicine if you are pregnant or plan to become pregnant.

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 this medicine if you are also taking monoamine oxidase inhibitors, a type of medicine used to treat depression, or if you have taken it in the last 14 days.

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.

Talk to your pharmacist or doctor if you are not sure whether you should start taking this medicine.

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 had any of the following medical conditions:

- high blood pressure
- overactive thyroid gland
- diabetes
- heart disease or poor blood flow in the blood vessels of the heart
- glaucoma (high pressure in the eyes)
- prostate problems
- liver or kidney disease
- asthma
- chronic obstructive airways disease
- pneumonia
- any other respiratory (breathing) conditions

Tell your pharmacist or doctor if you have a chronic cough.

This medicine may make your cough worse.

Tell your pharmacist or doctor if you have a condition that produces large amounts of mucus.

This medicine may make your condition worse.

Ask your pharmacist or doctor about taking DEMAZIN Cough Cold & Flu tablets if you are breastfeeding.

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

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.

If you have not told your pharmacist or doctor about any of the above, tell him/her before you start taking DEMAZIN Cough Cold & Flu.

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 DEMAZIN Cough Cold & Flu may interfere with each other. These include:

- medicines used to treat heart conditions
- medicines used to treat high blood pressure
- medicines used to treat urinary tract infections and bladder problems
- medicines used to treat depression or behavioural disorders
- phenylephrine, a medicine used to treat congestion
- appetite suppressants
- warfarin, a medicine used to prevent blood clots
- metoclopramide, a medicine used to control nausea and vomiting
- medicines used to treat epilepsy or fits
- chloramphenicol, an antibiotic used to treat ear and eye infections
- monoamine oxidase inhibitors, a medicine used to treat depression, especially if taken within the last 14 days
- quinidine and amiodarone, medicines used to treat abnormal or irregular heart beat
- opioid analgesics used to treat pain
- medicines used to help you relax, sleep or relieve anxiety, such as sedatives

These medicines may be affected by DEMAZIN Cough Cold & Flu or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

How to take DEMAZIN Cough Cold & Flu

DEMAZIN Cough Cold & Flu tablets are only available from your pharmacist.

Follow all directions given to you by your pharmacist or doctor carefully.

They may differ from the information contained in this leaflet.

Ask your pharmacist or doctor for help if you do not understand the instructions on the box.

How much to take

The recommended dose is:

Adults and children 12 years and over: 1-2 tablets

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.

When to take it

Take your dose every 6 to 8 hours, when necessary.

Do not take more than 8 tablets in 24 hours.

Do not take more than the recommended dose.

Pseudoephedrine sensitive individuals should take the last dose a few hours before bed time.

If you are sensitive to the effects of pseudoephedrine, you may experience sleeplessness if you take it just before going to bed.

How to take it

Swallow the tablet with a glass of water.

Do not crush or chew the tablet before swallowing.

How long to take it

Adults:

Take DEMAZIN Cold & Flu tablets for a few days at a time unless your doctor tells you to take it for longer.

Children 12 years & over:

Give DEMAZIN Cold & Flu tablets to children for up to 48 hours unless a doctor has told you to give it for longer.

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, 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 (telephone 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 many DEMAZIN Cough Cold & Flu tablets. You may need urgent medical attention.

While you are using DEMAZIN Cough Cold & Flu

Things you must do

Tell any doctor or pharmacist who is treating you that you are taking DEMAZIN Cough Cold & Flu tablets.

Keep to the recommended dose.

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 this medicine.

Things you must not do

Do not take DEMAZIN Cough Cold & Flu tablets to treat any other conditions 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.

Things to be careful of

Be careful driving or operating machinery until you know how DEMAZIN Cough Cold & Flu tablets affect you.

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

Only drink small quantities of alcohol (beer, wine or spirits) while taking DEMAZIN Cough Cold & Flu tablets.

Drinking large quantities of alcohol while taking medicines containing paracetamol may increase the risk of liver side effects.

Side effects

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.

Tell your pharmacist or doctor as soon as possible if you do not feel well while you are taking DEMAZIN Cough Cold & Flu tablets.

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.

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

- not passing any or very little urine
- 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
- excitation
- extreme confusion
- severe nausea and vomiting
- restlessness
- irritability
- nervousness and anxiety

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 any of the following and they worry you:

- drowsiness
- difficulty sleeping
- excitability
- restlessness
- dizziness
- fear or anxiety
- rapid heart beat
- tremor
- hallucinations
- constipation
- nervousness
- nausea, vomiting or dyspepsia
- fatigue
- stomach discomfort

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

Children and people over 65 years of age may have an increased chance of getting side effects.

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 DEMAZIN Cough Cold & Flu

Storage

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

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store DEMAZIN Cough Cold & Flu tablets 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

DEMAZIN Cough Cold & Flu is a round half inch diameter, shallow convex faced bevelled edge pale yellow tablet with break bar.

DEMAZIN Cough Cold & Flu is available in packs of 24's.

Ingredients

Each DEMAZIN Cough Cold & Flu tablet contains:

Active ingredients:

- pseudoephedrine hydrochloride 30 mg
- dextromethorphan hydrobromide 15 mg
- paracetamol 500 mg

Inactive ingredients

- Vegetable oil - hydrogenated
- Povidone
- Sodium starch glycollate
- Magnesium stearate
- Croscarmellose sodium
- Carnauba wax
- Starch - pregelatinised maize
- Cellulose microcrystalline
- 2472-Opadry Yellow OY-22920

This medicine does not contain lactose or gluten

Supplier

DEMAZIN Cough Cold & Flu tablets are supplied in Australia by:

Merck Sharp & Dohme (Australia) Pty Limited

54 - 68 Ferndell Street
South Granville
NSW 2142
AUSTRALIA

DEMAZIN Cough Cold & Flu tablets: AUST R 97031

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