

Demazin[®] Original Cold + Flu Relief Day + Night

Active ingredients:

Day Tablet: Paracetamol, Pseudoephedrine hydrochloride

Night tablet: Paracetamol, Pseudoephedrine hydrochloride, Chlorphenamine maleate

Consumer Medicine Information (CMI)

This leaflet provides important information about using Demazin Original Cold + Flu Relief Day + Night tablets. **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 Demazin.**

Where to find information in this leaflet:

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1. Why am I taking Demazin?

Demazin contains two different tablets. The white DAY tablet contains the active ingredients paracetamol and pseudoephedrine hydrochloride. The pink NIGHT tablet contains paracetamol, pseudoephedrine hydrochloride and chlorphenamine maleate.

Demazin is a cold and flu medicine. The Day tablets contain a decongestant and pain reliever. The Night tablet contains a decongestant, pain reliever and antihistamine. Pseudoephedrine hydrochloride is a decongestant and is used to relieve nasal congestion and runny nose. It works by reducing congestion in the upper respiratory tract, including the nose, nasal passages and sinuses, and making it easier to breathe.

Paracetamol is a pain reliever and works by blocking the pain messages from getting through to the brain. It also acts in the brain to reduce fever.

Chlorphenamine maleate is an antihistamine. Antihistamines help reduce allergic symptoms such as sneezing and itchy watery eyes 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.

Demazin is used to provide temporary relief from the following symptoms of cold and flu:

- runny nose
- sinus pain

- blocked nose and sinus
- fever
- headache
- body aches and pain.

The NIGHT tablet also aids rest by providing relief from:

- watery, itchy eyes
- sneezing.

2. What should I know before I take Demazin?

Warnings

Do not take Demazin if you:

- are allergic to paracetamol, pseudoephedrine, chlorphenamine, or any of the ingredients listed at the end of this leaflet.

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

- have any of the following conditions:
 - very high blood pressure
 - severe coronary artery disease (heart disease caused by poor blood flow or narrowing of the blood vessels of the heart)
 - narrow angle glaucoma (high pressure in the eyes)
 - stomach obstruction, including due to a peptic ulcer
 - enlarged prostate

- bladder obstruction.
- are taking a medicine for depression known as a monoamine oxidase inhibitor (MAOI) or if you have taken one in the past 14 days.

Check with your doctor or pharmacist if you:

- have any other medical conditions including:
 - high blood pressure
 - overactive thyroid
 - diabetes mellitus
 - heart disease
 - glaucoma
 - enlarged prostate
 - epilepsy
 - impaired kidney or liver function.
- take any medicines for any other condition, especially anti-depressant medication.

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 [6. Are there any side effects?](#)

Pregnancy and breastfeeding

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

Your doctor can discuss the risks and benefits of taking Demazin during pregnancy.

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

Demazin should not be used when breastfeeding. Paracetamol, pseudoephedrine and chlorphenamine pass into breast milk.

Use in children

- Demazin is not recommended for children under 12 years of age.

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 Demazin and affect how it works. These include:

- Medicines which may increase blood pressure including:
 - Tricyclic antidepressants and monoamine oxidase inhibitors (MAOIs).
 - Decongestants used in cold medications
 - Beta blockers and methyldopa used to lower blood pressure
 - Appetite suppressants
 - Phenytoin used for epilepsy
- Medicines which may increase the sedating effects of Demazin including:

- Medicines to help you sleep or relax
- Opioid pain killers
- Other medicines including:
 - Warfarin used to prevent blood clots. Your warfarin dose may require reduction if you use this product for a long period of time.
 - Probenecid used for gout
 - Medicines for urinary tract infections or bladder problems
 - Colestyramine used to lower cholesterol
 - Metoclopramide used to control nausea and vomiting.

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

4. How do I take Demazin?

How much to take

- Follow the instructions provided with the medicine.
- Take 2 white DAY tablets morning and afternoon if necessary.
- Take 2 pink NIGHT tablets at bedtime if necessary.
- Do not exceed the recommended dosage. The maximum dose is 6 DAY tablets and 2 NIGHT tablets in 24 hours.

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 this medicine.

If you take too much Demazin

If you think that you have used too much Demazin, 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 because of the risk of delayed, serious liver damage.

5. What should I know while taking Demazin?

Things you should do

If symptoms persist, see your doctor or pharmacist.

Unless advised by your doctor, Demazin should not be used for more than a few days at a time in adults and in children aged between 12 and 17 years for more than 48 hours.

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

Things you should not do

- Do not take Demazin with any other cold and flu medicines unless your doctor or pharmacist has advised you to.
- Do not take Demazin with any other paracetamol containing products unless your doctor or pharmacist has advised you to.

Driving or using machines

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

The NIGHT tablets may cause drowsiness and may increase the effects of alcohol. Drowsiness may continue the following day. If you are affected do not drive or operate machinery.

Drinking alcohol

Tell your doctor or pharmacist if you drink alcohol.

Alcohol may increase the sedative effects of this medicine making you more drowsy.

Looking after your medicine

- Store 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

Less serious side effects	What to do
<ul style="list-style-type: none">• drowsiness or sleepiness• difficulty sleeping• dizziness• restlessness• excitability	Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
<ul style="list-style-type: none"> ● nervousness and irritability ● hallucinations ● fear or anxiety ● fast heartbeat ● tremor ● twitching or jerking muscles ● impaired coordination and reduced motor skills ● dry mouth, nose, and throat ● constipation ● nausea or vomiting. 	

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> ● Sudden, severe abdominal pain, especially if accompanied by blood in your stools. ● Signs of an allergic reaction including: 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ○ 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. ● Not passing any or very little urine. 	

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.

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 www.tga.gov.au/reporting-problems. 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 Demazin contains

Day Tablet

Active ingredients (main ingredients)	Paracetamol Pseudoephedrine hydrochloride
Other ingredients (inactive ingredients)	Microcrystalline cellulose Crospovidone Magnesium stearate Povidone Pregelatinised maize starch Stearic acid

Night Tablet

Active ingredients (main ingredients)	Paracetamol Pseudoephedrine hydrochloride Chlorphenamine maleate
Other ingredients (inactive ingredients)	Microcrystalline cellulose Crospovidone Magnesium stearate Povidone

	Pregelatinised maize starch Stearic acid Erythrosine
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Do not take this medicine if you are allergic to any of these ingredients.

What Demazin looks like

Demazin Original Cold + Flu Relief Day + Night contains a Day tablet and a Night tablet.

The Day tablet is a white round tablet with a break line.

The Night tablet is a pink round tablet with a break line.

Each pack contains 16 day tablets and 8 night tablets.

Registration number: AUST R 286002.

Who distributes Demazin

iNova Pharmaceuticals (Australia) Pty Limited

Level 10, 12 Help Street

Chatswood NSW 2067

Tel: 1800 630 056

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