Demazin® Original 6 hour Relief

Active ingredients: Pseudoephedrine sulfate and chlorphenamine maleate

Consumer Medicine Information (CMI)

This leaflet provides important information about using Demazin Original 6 hour Relief 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:

- 1. Why am I taking Demazin?
- 2. What should I know before I take Demazin?
- 3. What if I am taking other medicines?
- 4. How do I take Demazin?
- 5. What should I know while taking Demazin?
- 6. Are there any side effects?
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1. Why am I taking Demazin?

Demazin contains a combination of two active ingredients pseudoephedrine sulfate and chlorphenamine maleate.

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

Chlorpheniramine maleate is an antihistamine. Antihistamines help reduce allergic symptoms such as sneezing or watery, itchy 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 provides relief from:

- runny nose
- blocked nose and sinus
- sneezing
- watery, itchy eyes

associated with the common cold, nasal allergy, hayfever and sinusitis.

2. What should I know before I take Demazin?

Warnings

Do not take Demazin if you:

 are allergic to pseudoephedrine or 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 very high blood pressure
- have severe coronary artery disease (heart disease caused by poor blood flow or narrowing of the blood vessels of the heart)

 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:
 - o narrow angle glaucoma (high pressure in the eyes)
 - o high blood pressure
 - heart disease
 - stomach obstruction, including due to a peptic ulcer
 - enlarged prostate
 - bladder obstruction
 - o diabetes
 - o overactive thyroid.
- take any medicines for any other condition.

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</u>. Are there any side effects?

Pregnancy and breastfeeding

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

Demazin should only be taken during pregnancy if the benefits of taking it outweigh the potential risks to your developing baby.

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

Demazin may pass into breast milk.

Use in children

This medicine should not be given to children under 12 years of age, including newborn and premature babies.

Chlorphenamine can cause restlessness and excitability in children.

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.

Medicines that may <u>increase</u> the effect of Demazin include:

- medicines used to treat depression, especially monoamine oxidase inhibitors (MAOIs) and tricyclic antidepressants
- medicines used to help you sleep or relax (sedatives and hypnotics)
- opioid analgesics used to relieve pain.

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

- Take 1 tablet every 6 hours, when required.
- Follow the instructions provided with the medicine.
- 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.

Elderly patients are more likely to have side effects from taking this medicine.

When to take Demazin

- Demazin should not be used more than once every 6 hours
- Avoid taking Demazin close to bedtime. Demazin can cause sleeplessness if taken up to several hours before going to bed.

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.

5. What should I know while taking Demazin?

Things you should do

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

See your doctor or pharmacist if symptoms persist for more than a few days.

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.

Driving or using machines

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

Demazin may cause dizziness and/or sleepiness in some people. If this happens, 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 25°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
 drowsiness trouble sleeping nausea dizziness headache impaired coordination, fine motor skills. and balance rapid heartbeat or palpitations dilated pupils. 	Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
 Sudden, severe abdominal pain, especially if accompanied by blood in your stools. Signs of an allergic reaction including: 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. 	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.

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

Active ingredients (main ingredients)	Pseudoephedrine sulfate Chlorphenamine maleate
Other ingredients (inactive ingredients)	Brilliant Blue CFC Starch maize Magnesium stearate Povidone
Patantial allaman	Lactose
Potential allergens	Lactose

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

What Demazin looks like

Demazin is a round, convex, blue tablet, plain on one side and with a score line on the other side.

Registration number: AUST R 18815

Who distributes Demazin

iNova Pharmaceuticals (Australia) Pty Limited

Level 10, 12 Help Street

Chatswood NSW 2067

Tel: 1800 630 056

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