

DEMAZIN Day & Night Cold & Flu Tablets

Day tablets: Pseudoephedrine hydrochloride, paracetamol and codeine phosphate;

Night tablets: Pseudoephedrine hydrochloride, paracetamol and chlorpheniramine maleate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DEMAZIN Day & Night Cold & Flu tablets. It does not contain all the available information and it does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your pharmacist or doctor has weighed the risks of you taking DEMAZIN Day & Night 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 want to read it again later.

What DEMAZIN Day & Night Cold & Flu is used for

DEMAZIN Day & Night Cold & Flu tablets provide effective temporary relief from the following symptoms of cold & flu:

- runny nose
- sinus pain
- blocked nose & sinus
- fever
- headache
- body ache & pain

In addition, the Night tablet aids rest by providing relief from:

- watery, itchy eyes
- sneezing

DAY tablet contains a combination of three medicines: pseudoephedrine hydrochloride, paracetamol and codeine phosphate.

NIGHT tablet contains a combination of three medicines: pseudoephedrine hydrochloride, paracetamol and chlorpheniramine maleate.

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.

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

Codeine phosphate belongs to a group of medicines called analgesics. It is an opioid analgesic and it acts by blocking pain and your emotional response to pain.

Chlorpheniramine maleate belongs to a group of medicines called 'antihistamines'. Antihistamines help reduce allergic symptoms 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.

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 use DEMAZIN Day & Night Cold & Flu

When you must not take it

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

- any medicine containing pseudoephedrine hydrochloride, paracetamol, codeine phosphate, chlorpheniramine maleate
- 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 have or have had any of the following medical 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)
- glaucoma (high pressure in the eyes)
- stomach or duodenal ulcer, or other stomach problems
- prostate problems
- bladder problems
- chronic constipation
- diarrhoea caused by antibiotics or poisoning

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 give this medicine to newborn or premature babies.

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 have 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
- breathing problems
- a history of drug dependence, including alcohol dependence
- recent surgery on the stomach or intestines
- head injury
- epilepsy

Ask your pharmacist or doctor about taking DEMAZIN Day & Night 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 Day & Night Cold & Flu tablets.

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

- medicines used to treat depression, especially monoamine oxidase inhibitors and tricyclic antidepressants
- medicines used to help you sleep or relax (sedatives and hypnotics)
- opioid analgesics, medicines used to treat pain
- phenytoin, a medicine used to treat epilepsy or fits
- medicines used to treat heart conditions
- quinidine, a medicine used to treat abnormal or irregular heart beat
- medicines used to treat high blood pressure
- medicines used to treat urinary tract infections and bladder problems
- medicines for diarrhoea, such as kaolin, pectin and loperamide
- phenothiazines and antipsychotic agents, medicines used to treat mental 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
- chloramphenicol, an antibiotic used to treat ear and eye infections

These medicines may be affected by DEMAZIN Day & Night 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 Day & Night Cold & Flu

DEMAZIN Day & Night 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 doses are:

Adults and children over 12 years:

- DAY tablet: 2 tablets in the morning and again in the afternoon, when necessary.
- NIGHT tablet: 2 tablets at bedtime, when necessary.

Not recommended for children under 12 years of age.

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

Swallow tablet whole with a glass of water.

DEMAZIN Day & Night Cold & Flu tablets can be taken with or without food.

How long to take it

Adults:

Do not take this medicine for longer than a few days at a time unless advised to by a doctor.

Children 12 years and over:

Do not take this medicine for longer than 48 hours at a time unless advised to by a doctor.

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 Day & Night Cold & Flu tablets.

You may need urgent medical attention.

While you are using DEMAZIN Day & Night Cold & Flu

Things you must do

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

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 with other medicines containing paracetamol unless advised to do so by a doctor.

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.

Do not drink alcohol while taking DEMAZIN day & Night Cold & Flu tablets

Drinking alcohol while taking this medicine will make you more drowsy and may increase the risk of liver side effects.

Things to be careful of

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

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

Do not take high doses of the medicine for long periods of time unless your doctor tells you to.

Codeine may be habit forming if taken frequently and over a long period. Codeine may cause constipation.

About 8% of people are poor metabolisers of codeine and DEMAZIN Day & Night Cold & Flu tablets may not work as well if you are one of those people.

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 Day & Night 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

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor as soon as possible if you notice any of the following:

- unusual or extreme mood swings
- flushing of the face
- difficult or painful urination
- seizures (fits)

The above list includes serious side effects that may require medical attention. These side effects are rare.

Tell your pharmacist or doctor if you notice any of the following and they worry you:

- drowsiness or sleepiness
- difficulty sleeping
- excitability
- restlessness
- dizziness
- fear or anxiety
- rapid/fast heart beat
- tremor
- hallucinations

- dry mouth, nose and throat
- constipation
- nervousness and irritability
- twitching or jerking muscles
- nausea or dyspepsia
- vomiting

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 Day & Night Cold & Flu

Storage

Keep your tablets in the original blister pack until it is time to take them.

If you take the tablets out of the blister pack they may not keep well.

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

Do not store DEMAZIN Day & Night Cold & Flu tablets or any other medicine in the bathroom or near a sink. Do not leave them 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 or 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 Day & Night Cold & Flu contains DAY and NIGHT tablets.

- **DAY tablet -**
A white, clear, film-coated, small capsule-shaped tablet with a break bar on one side with the letters 'CF' and 'SH', and plain on the other.
- **NIGHT tablet -**
A blue, clear, film-coated, small, capsule-shaped tablet with a break bar on one side with the letters 'SH', and plain on the other.

DEMAZIN Day & Night Cold & Flu is available in pack of 24's. Each pack contains 16 DAY tablets and 8 NIGHT tablets.

Ingredients

Each DAY tablet contains:

Active ingredients

- Pseudoephedrine hydrochloride 30 mg
- Paracetamol 500 mg
- Codeine phosphate 9 mg

Inactive ingredients

- Povidone
- Croscarmellose sodium
- Silica - colloidal anhydrous
- Magnesium stearate
- Starch maize
- Cellulose-microcrystalline

- Stearic acid
- Hypromellose
- Macrogol 400
- Carnauba wax

Each NIGHT tablet contains:

Active ingredients

- Chlorpheniramine maleate 2 mg
- Pseudoephedrine hydrochloride 30 mg
- Paracetamol 500 mg

Inactive ingredients

- Povidone
- Croscarmellose sodium
- Silica - colloidal anhydrous
- Magnesium stearate
- Starch maize
- Cellulose-microcrystalline
- Stearic acid
- Hypromellose
- Macrogol
- Brilliant Blue FCF CI42090 (133)
- Titanium dioxide (171)
- Carnauba wax

Supplier

DEMAZIN Day & Night Cold & Flu tablets are supplied in Australia by:

Merck Sharp & Dohme (Australia) Pty Limited

54 - 68 Ferndell Street
South Granville
NSW 2142
AUSTRALIA

DEMAZIN Day & Night Cold & Flu tablets:
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