

ANTINAUS

Prochlorperazine maleate tablets 5 mg



What is in this leaflet

This leaflet answers some common questions about Antinaus.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Antinaus against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Antinaus is used for

Antinaus is used for the treatment and/or prevention of nausea and vomiting. Antinaus is also used for migraine, vertigo, schizophrenia (particularly in the chronic stage), acute mania and in the short term management of anxiety.

Antinaus contains the active ingredient prochlorperazine maleate. It belongs to a group of medicines called phenothiazines.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

Antinaus is not recommended for children under 2 years of age or children under 10 kg in weight.

Antinaus is available on prescription from your doctor.

Before you take Antinaus

Do not take Antinaus if you have an allergy to:

- any medicine containing prochlorperazine or phenothiazines
- 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.

You should not take Antinaus if you have any of the following medical conditions:

- shock
- disease of the blood with a low number of blood cells (bone marrow depression)

Do not give this medicine to a child under the age of 2 years or who weighs less than 10 kg.

Safety and effectiveness in children younger than 2 years have not been established.

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.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it:

Tell your doctor if you have any risk factors for stroke, such as heart problems (including irregular heart beats or high blood pressure), high blood cholesterol or vascular problems (stroke or clot).

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Tell your doctor if you have or have had any of the following medical conditions:

- liver problems
- kidney problems
- low blood pressure
- epilepsy or seizures
- Parkinson's disease (a disease with muscle rigidity, tremor and slowing of physical movement)
- hypothyroidism (an underactive thyroid gland)
- pheochromocytoma (a rare tumour of the adrenal gland)
- myasthenia gravis (a disease of weakness and fatigue of the muscles causing drooping eyelids and double vision, difficulty in speaking and swallowing, and weakness of limbs)
- prostate hypertrophy (an enlarged prostate)
- low blood calcium levels
- glaucoma (high pressure in the eye)
- neuroleptic malignant syndrome (a reaction to some medicines with a sudden increase in body temperature, extremely high blood pressure and severe convulsions)
- a previous reaction to any medicine which was characterized by repetitive,

- involuntary, purposeless movements (tardive dyskinesia)
- dementia
- diabetes or an intolerance to glucose

If you have not told your doctor about any of the above, tell him/her before you start taking Antinaus.

Taking other medicines

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

Do not take any medicines that cause drowsiness while you are taking Antinaus.

Some medicines and Antinaus may interfere with each other. These include:

- medicines used to treat irregular heart beats (e.g. quinidine, disopyramide, amiodarone, sotalol)
- medicines which slow the heart beat (e.g. diltiazem, verapamil, beta-blockers, clonidine, digitalis)
- medicines which lower potassium blood levels (e.g. fluid tablets, laxatives)
- antipsychotic medicines (used to treat certain mental and emotional conditions)
- lithium
- over-the-counter cough, cold, or allergy medications; sleep aids; antidepressants; muscle relaxants; barbiturates; and other sedatives (these drugs may increase the side effects of Antinaus, especially drowsiness and dizziness)
- anticholinergic medicines which are used to relieve stomach cramps, spasms and travel sickness (e.g. atropine, benztropine, hyoscine)
- blood pressure medications (these medicines may cause dizziness and fainting if used with Antinaus), including guanethidine

- medicines used to treat Parkinson's disease (e.g. levodopa)
- adrenaline
- amphetamine
- desferrioxamine (used to treat high iron levels in the body)
- oral anticoagulants (medicines used to prevent blood clots or to thin the blood)
- procarbazine (an anticancer medicine)
- some medicines used to control epilepsy, including phenytoin

These medicines may be affected by Antinaus 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 have more information on medicines to be careful with or avoid while taking this medicine.

How to take Antinaus

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

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

The usual dose for adults is:

- For the **prevention** of nausea and vomiting: **ONE** or **TWO** tablets, two or three times daily
- For the **treatment** of nausea and vomiting: **FOUR** tablets at once as a single dose. If necessary, take **TWO** additional tablets no sooner than two hours later.
- For use in vertigo and Meniere's disease: **ONE** tablet three times daily. If necessary, your doctor may increase this dose to a

maximum of **SIX** tablets daily.

- For use in the short-term management of anxiety: **TWO** to **FOUR** tablets daily in divided doses. If necessary, your doctor may increase this dose to a maximum of **EIGHT** tablets daily in divided doses.
- For use in schizophrenia and other psychotic disorders: the usual effective daily dosage is **75 – 100 mg** (15 – 20 tablets) daily.

Antinaus is not recommended for use in children under 2 years of age or below 10 kg in weight.

How to take it

Swallow the tablets with a full glass of water.

It does not matter if you take this medicine with or without food.

When to take it

Take your medicine at about the same time(s) each day.

Taking it at the same time(s) each day will have the best effect. It will also help you remember when to take it.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

If you forget a dose, just take the next dose when it is due.

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 doctor or pharmacist.

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 National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Antinaus. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose may include drowsiness, restlessness, confusion, excitement, low blood pressure, a fast heart beat, tremor, muscle twitching, seizures, difficulty in swallowing or breathing and coma.

While you are using Antinaus

Things you must do

Tell your doctor immediately if you notice any uncontrolled movements of the tongue, face, mouth or jaw such as puffing of the cheeks, puckering of the mouth or chewing movements.

These are symptoms of a very rare condition called tardive dyskinesia, which may develop in people taking phenothiazine medicines, including Antinaus. The condition is more likely to occur during long term treatment with Antinaus, particularly in elderly women.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Antinaus.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take Antinaus to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects. If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

Things to be careful of

Be careful driving or operating machinery until you know how Antinaus affects you.

This medicine may cause dizziness, light-headedness, tiredness and drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol, the dizziness and light-headedness may be worse. Your doctor may suggest you avoid alcohol while you are being treated with Antinaus.

If outdoors, wear protective clothing and use at least a 15+ sunscreen.

Antinaus may cause your skin to be much more sensitive to sunlight than it is normally. Exposure to sunlight may cause a skin rash, itching, redness, or severe sunburn. If your skin appears to be burning, tell your doctor.

Make sure you keep cool in hot weather and keep warm in cool weather.

Antinaus may affect the way your body reacts to temperature changes.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Antinaus.

This medicine helps most people but it may have unwanted side effects in a few people. 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.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

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

- dizziness
- dry mouth
- mild restlessness
- trembling, rigid posture, slow movements and a shuffling unbalanced walk
- constipation
- blurred vision
- drowsiness
- twitching

The above list includes the more common side effects of your medicine.

The following side effects are less common:

- low blood pressure
- swelling of hands and feet
- for females: unusual secretion of breast milk, irregular periods
- for males: breast enlargement, difficulty in ejaculating
- severe pain in the stomach with bloating, cramps and vomiting
- difficulty in passing urine
- trouble sleeping
- headache

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

- swelling of your face, lips or tongue; difficulty swallowing or breathing; or hives
- a skin rash
- yellowing of the skin or eyes, also called jaundice
- sudden onset of fever
- severe drowsiness or fainting
- severe restlessness or tremor
- muscle spasms of the face, neck or back
- uncontrollable movements of the tongue, face, lips, arms, or legs
- fast or irregular heart beat
- seizures
- unusual muscle tone or spasms causing distortions of the body in children

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

The list of side effects mentioned above is not complete. If you should suffer from any of these side effects or any other undesired effect please tell your doctor or pharmacist.

After using Antinaus

Storage

Keep your tablets in the pack until it is time to take them. If you take the tablets out of the pack they may not keep well.

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

Do not store Antinaus 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

If your doctor or pharmacist tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Antinaus are white biconvex tablets (7.1 mm in diameter) imprinted "PM" breakline over "5" on one side.

Antinaus comes in a pack containing 500 tablets.

Ingredients

Antinaus contains 5 mg of prochlorperazine maleate as the active ingredient.

It also contains:

- lactose
- magnesium stearate
- povidone
- microcrystalline cellulose
- maize starch

This medicine does not contain gluten.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.

Telephone: (09) 579 2792

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4 October 2010
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