

ANTINAUS

Prochlorperazine maleate 5mg tablets

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. You may need to read it again.

What ANTINAUS is used for and how it works

Your ANTINAUS tablets contain prochlorperazine maleate. It belongs to a group of medicines known as phenothiazines.

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.

Your doctor may, however, prescribe ANTINAUS for another reason. Ask your doctor if you have any questions about why ANTINAUS has been prescribed for you.

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

When you must not take it

Do not take ANTINAUS if you have any of the following:

- an allergy to medicines containing prochlorperazine or phenothiazines
- an allergy to any of the ingredients listed at the end of this leaflet

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 pregnant or breastfeeding.

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 has 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.

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

Before you take it

Tell your doctor or pharmacist 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)**
- **you are pregnant, plan to become pregnant, or are breastfeeding**
- **you have allergies to any other medicines, foods, preservatives or dyes.**

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

- liver problems
- kidney problems
- 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)
- 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.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any you get without a prescription from a 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:

- **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** (eg. atropine, benztropine, hyoscine)
- **blood pressure medications** (these medicines may cause dizziness and fainting if used with ANTINAUS)
- **medicines used to treat Parkinson's disease** (eg. levodopa)
- **lithium**
- **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.**

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 or pharmacist has more information on medicines to be careful with or avoid while taking ANTINAUS.

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 or bottle, 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 – 100mg (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

Take with a glass of water. ANTINAUS can be taken with or without food.

If you forget a dose

If you forget a dose, just take the next dose when it is due. Do not take more than one dose at a time to make up for missed doses.

While you are taking 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 plan to have surgery that needs a general anaesthetic, tell your doctor, anaesthetist or dentist that you are taking ANTINAUS.

If you are a woman of child-bearing age, you should avoid becoming pregnant while taking ANTINAUS. Tell your doctor immediately if you become pregnant in the same month as taking ANTINAUS.

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

Tell all doctors, dentists and pharmacists who treat you that you are taking ANTINAUS.

Things you must not do

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

Do not use ANTINAUS to treat any other medical complaints.

Do not stop taking ANTINAUS suddenly, your condition may worsen or your chance of getting an unwanted side effect may increase. To prevent this, your doctor may gradually reduce the amount of ANTINAUS you take each day before stopping completely.

Things to be careful of

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

As with other medicines ANTINAUS may cause dizziness, light-headedness, tiredness and drowsiness in some people.

If ANTINAUS makes you feel light-headed, dizzy or faint be careful when getting up from a sitting or lying position. Getting up slowly may help.

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.

All medicines can have some unwanted effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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 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, difficult in ejaculating
- severe pain in the stomach with bloating, cramps and vomiting
- difficulty in passing urine
- headache

Tell your doctor immediately if you notice any of the following:

- 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

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

- Unusual muscle tone or spasms causing distortions of the body in children.

These side effects are very rare but very serious and may need urgent medical attention or hospitalisation.

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.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

In case of overdose

Immediately contact your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) or go to the Emergency department at your nearest hospital, if you think that you may have taken too much, or if anyone else has taken ANTINAUS by mistake. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Take the pack of ANTINAUS with you if you can.

Keep telephone numbers for these places handy.

Storage conditions

Do not take this medicine after the expiry date shown on the pack or if the packaging shows signs of tampering.

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

Store your ANTINAUS tablets below 25°C. Protect from light. Keep out of reach of children.

Do not store ANTINAUS, or any other medicine, in the bathroom or near a sink.

Disposal

If you do not take your ANTINAUS tablets or they have passed the expiry date, ask your pharmacist what to do with the remaining medicine.

List of ingredients

Each tablet contains 5mg of the active ingredient, prochlorperazine maleate.

The tablet also contains lactose, magnesium stearate, povidone, microcrystalline cellulose, and maize starch.

If you want to know more

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

Who supplies this medicine

Marketed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11-183,
Ellerslie,
Auckland.
Telephone: 09 579 2792

Date of Information

2 December 2009

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