

NAUSETIL

Prochlorperazine maleate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Nausestil. 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 or pharmacist has weighed the risks of you taking Nausestil 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 NAUSETIL is used for

Nausestil contains the active ingredient prochlorperazine maleate and is used to treat nausea associated with migraine (severe headache).

Nausestil belongs to a group of medicines called phenothiazines, which help to correct chemical imbalances in the brain allowing it to function correctly. These chemicals may also affect the parts of the brain which control nausea.

There is no evidence that it is addictive.

Before you take it

When you must not take it

Do not take Nausestil if you have ever had an allergic reaction to:

- prochlorperazine maleate
- the group of medicines called phenothiazines
- any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include asthma, wheezing, shortness of breath, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, skin rash, itching or hives.

Do not take Nausestil if you have any of the following medical conditions:

- shock
- disease of the blood with a low number of blood cells
- jaundice, yellowing of the skin and/or eyes.

Nausestil must not be given to anyone who is unconscious or in a coma.

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

Do not give Nausestil to children under the age of two (2) years or under 10 kg in weight.

Do not take it after the expiry date (EXP) printed on the pack.

Do not take it if the packaging is torn or shows signs of tampering.

Talk to your doctor or pharmacist if you are not sure whether you should start taking Nausestil.

Before you start to take it

Tell your doctor or pharmacist if you are allergic to any other medicines or any foods, dyes or preservatives.

Tell your doctor if you are pregnant or intend to become pregnant.

Like most phenothiazine medicines, Nausestil is not recommended for use during pregnancy. If there is a need to take this medicine during your pregnancy, your doctor will discuss with you the benefits and risks of taking it.

Tell your doctor or pharmacist if you are breastfeeding or plan to breastfeed.

It is not recommended to take Nausestil while breastfeeding as it is not known whether it passes into breast milk.

Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:

- pheochromocytoma, a rare tumour of the adrenal glands which sit near the kidneys
- Parkinson's disease, a disease of the brain affecting movement which causes trembling, rigid posture, slow movement and a shuffling, unbalanced walk
- myasthenia gravis, a disease of the muscles causing drooping eyelids, double vision, difficulty in speaking and swallowing and sometimes muscle weakness in the arms or legs
- kidney problems
- heart and blood vessel problems, low blood pressure, blood clots
- liver disease
- prostate problems
- epilepsy, seizures or fits
- low blood calcium levels
- an underactive thyroid gland
- glaucoma, a condition in which there is usually a build-up of fluid 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 reaction to some medicines with uncontrollable twitching or jerking movements of the arms and legs
- dementia (especially in the elderly)
- high blood sugar levels.

Tell your doctor if you are about to have any surgery which requires a general anaesthetic.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Nausestil.

Taking other medicines

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

Some medicines may be affected by Nausestil or may affect how well it works. You may need to take different amounts of your medicines or you may need to take different medicines. Your doctor or pharmacist has a more complete list of medicines to avoid while taking Nausestil. These include:

- some medicines used to control depression or mood swings
- alcohol
- desferrioxamine, a drug used in iron overdose
- procarbazine, an anticancer drug

- some medicines used to control epilepsy
- medicines used to treat Parkinson's disease
- anticholinergic medicines which are used to relieve stomach cramps, spasms and travel sickness
- atropine, a medicine which may be used in some eye drops or cough and cold preparations
- medicines that prevent blood clotting
- medicines used to treat high blood pressure and fluid build-up in your body
- bepridil, cisapride, sultopride, thioridazine, methadone, erythromycin injection, vincamine injection, halofantrine, pentamidine, sparfloxacin, amphotericin B injection, glucocorticoids, tetracosactides
- certain laxatives.

How to take it

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

They may differ from the information contained in this leaflet.

How much to take

Your doctor or pharmacist will tell you how much Nausestil you will need to take each day. This depends on your condition and whether or not you are taking any other medicines.

For adults, the usual recommended dose is 1 or 2 tablets two to three times daily. For acute treatment, 4 tablets at once, followed if necessary by 2 tablets two hours later, may be taken.

Children (over the age of two (2) years or over 10 kg), the elderly or patients who have a pre-existing liver condition may need to take fewer tablets.

How to take it

Swallow the tablet whole with a full glass of water.

Do not chew the tablet.

When to take it

It does not matter if you take Nausestil before or after food.

If you take too much (overdose)

Do not try to vomit.

Immediately telephone your doctor or pharmacist or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much Nausestil. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of overdose may include the following:

- coma
- restlessness, shaking, muscle twitching, muscle weakness, spasm
- confusion
- excitement or agitation
- low blood pressure
- fast heart beat
- decrease in body temperature
- small pupils in the eye

- difficulty in swallowing or breathing
- blue skin.

While you are taking it

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 Nausestil.

The condition is more likely to occur during long term treatment, especially in elderly women. In very rare cases, this may be permanent.

Tell any other doctors, dentists and pharmacists who are treating you that you are taking Nausestil.

If you are about to be started on any new medicines, tell your doctor, dentist or pharmacist that you are taking Nausestil.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking this medicine.

Tell your doctor or pharmacist immediately if you become pregnant while taking Nausestil.

Things you must not do

Do not give Nausestil to children under the age of two (2) years or under 10 kg in weight.

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

Do not take it to treat any other complaints unless your doctor or pharmacist tells you to.

Things to be careful of

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

As with other medicines, Nausestil may cause dizziness, light-headedness, tiredness and drowsiness in some people, especially in the first few days of treatment.

If Nausestil makes you feel light-headed, dizzy or faint, get up slowly from a sitting or lying position.

Be careful when drinking alcohol while taking Nausestil.

If you drink alcohol, dizziness or light-headedness may be worse.

Your doctor or pharmacist may suggest you avoid alcohol while you are being treated with Nausestil.

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

Nausestil 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.

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

Nausestil 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 Nausestil.

Nausestil helps most people with nausea associated with migraine, 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 treatment if you get some of the side effects.

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

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

- constipation
- dry mouth
- drowsiness
- restlessness
- trembling, rigid posture, mask-like face, slow movements and a shuffling unbalanced walk
- twitching
- blurred vision.

The following side effects are less common:

- dizziness, light-headedness
- changes in heart beat
- swelling of the hands, ankles or feet
- itchy skin rash
- for females: unusual secretion of breast milk, irregular periods
- for males: breast enlargement, difficulty in ejaculating
- severe pain in the stomach with bloating, gut cramps and vomiting
- difficulty passing urine
- yellowing of the skin and/or eyes
- headache
- insomnia
- seizures
- difficulty in breathing
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal
- excessive thirst
- dry mouth and skin
- changes in vision.

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

- unusual muscle tone or spasms causing distortion of the body in children
- chest pain and shortness of breath.

These are very serious side effects. Serious side effects are rare.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may occur in some people.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After taking it

Storage

Keep your tablets in a cool dry place, protected from light where the temperature stays below 30°C.

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

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

Keep it where young 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

Return any unused medicine to your pharmacist.

Product Description

What it looks like

Nausestil tablets are round, pale yellow tablets engraved with "M" on one side and plain on the other. They are available in packs of 10 tablets.

Ingredients

Active ingredient:

Each tablet contains 5 mg of prochlorperazine maleate.

Inactive ingredients:

- wheat starch
- calcium hydrogen phosphate
- magnesium stearate
- sodium lauryl sulfate
- quinoline yellow.

Nausestil tablets do not contain sucrose or lactose.

Sponsor

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Australian Registration Number:
AUST R 159537

This leaflet was prepared in June 2010.