

Consumer Medicine Information (CMI) summary

The [full CMI on the next page](#) has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using NAUSETIL?

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

For more information, see Section [1. Why am I using NAUSETIL?](#) in the full CMI.

2. What should I know before I use NAUSETIL?

Do not use if you have ever had an allergic reaction to NAUSETIL or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use NAUSETIL?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with NAUSETIL and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use NAUSETIL?

- Your doctor or pharmacist will tell you how much NAUSETIL you will need to take each day.
- For adults, the usual recommended dose is 1 or 2 tablets two to three times daily.

More instructions can be found in Section [4. How do I use NAUSETIL?](#) in the full CMI.

5. What should I know while using NAUSETIL?

Things you should do	<ul style="list-style-type: none"> Remind any doctor, dentist or pharmacist you visit that you are using NAUSETIL. Tell your doctor 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. If outdoors, wear protective clothing and use at least a SPF 15+ sunscreen.
Things you should not do	<ul style="list-style-type: none"> Do not give NAUSETIL to children and adolescents under 18 years of age.
Driving or using machines	<ul style="list-style-type: none"> Be careful driving or operating machinery until you know how NAUSETIL affects you. It may cause dizziness, light-headedness, tiredness and drowsiness especially in the first few days of treatment
Drinking alcohol	<ul style="list-style-type: none"> Be careful when drinking alcohol while taking NAUSETIL. If you drink alcohol, dizziness or lightheadedness may be worse.
Looking after your medicine	<ul style="list-style-type: none"> Keep your tablets in a cool dry place that is protected from light.

For more information, see Section [5. What should I know while using NAUSETIL?](#) in the full CMI.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking NAUSETIL. Some common side effects include constipation, dry mouth, drowsiness, trembling, rigid posture, twitching and blurry vision.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

NAUSETIL

Active ingredient(s): *Prochlorperazine maleate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using NAUSETIL. **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 NAUSETIL.**

Where to find information in this leaflet:

- [1. Why am I using NAUSETIL?](#)
- [2. What should I know before I use NAUSETIL?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use NAUSETIL?](#)
- [5. What should I know while using NAUSETIL?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using NAUSETIL?

NAUSETIL contains the active ingredient **prochlorperazine maleate**. NAUSETIL is a phenothiazine, which helps 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.

NAUSETIL is used to treat nausea associated with **migraine (severe headache)**.

There is no evidence that it is addictive.

2. What should I know before I use NAUSETIL?

Warnings

Do not use NAUSETIL if:

- you are taking other medicines that cause drowsiness
- you have medical conditions such as:
 - shock
 - disease of the blood with a low number of blood cells
 - being unconscious or in a coma
- you are allergic to prochlorperazine, the group of medicines called phenothiazines, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

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.

Check with your doctor if you:

Have any other medical conditions

- phaeochromocytoma, 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.
- agranulocytosis, which affects blood count
- schizophrenia, a mental illness.

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 [6. Are there any side effects?](#)

Pregnancy and breastfeeding

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

Like most phenothiazine medicines, NAUSETIL 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.

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

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

Use in Elderly

NAUSETIL should be used with caution in the elderly particularly during very hot or very cold weather.

The elderly is more likely to experiencing dizziness and drowsiness.

Use in Children

NAUSETIL is not recommended for use in children and adolescents under 18 years of age.

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 NAUSETIL and affect how it works. These include:

- some medicines used to control depression, mood swings or mental illness such as lithium
- alcohol
- desferrioxamine, a drug used in iron overdose
- certain anticancer medicines such as procarbazine
- 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 such as guanethidine, clonidine
- medicines that treat heart conditions
- certain laxatives
- some antibiotics
- amphetamine, a stimulant drug
- adrenaline, bepridil, cisapride, sultopride, thioridazine, methadone, erythromycin injection, vincamine injection, halofantrine, pentamidine, sparfloxacin, amphotericin B injection, glucocorticoids, tetracosactides (tetracosactrin).

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect NAUSETIL.

4. How do I use NAUSETIL?

How much to take

- Your doctor or pharmacist will tell you how much NAUSETIL 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.
- The elderly or patients who have a pre-existing liver condition may need to take fewer tablets.

When to take NAUSETIL

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

How to take NAUSETIL

- Swallow the tablet whole with a full glass of water.
- Do not chew the tablet.

If you use too much NAUSETIL

If you think that you have used too much NAUSETIL, 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.

Symptoms of overdose may include tiredness, coma, restlessness, shaking, muscle twitching, muscle weakness, spasm, confusion, excitement or agitation, low blood pressure, fast heart beat, decrease body temperature, small pupils in the eye, difficulty in swallowing or breathing, or blue skin, difficulty speaking, or convulsions.

5. What should I know while using NAUSETIL?

Things you should do

- If outdoors, wear protecting clothing and use at least a SPF 15+ sunscreen. NAUSETIL 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. NAUSETIL may affect the way your body reacts to temperature changes.
- If NAUSETIL makes you feel light-headed, dizzy or faint, get up slowly from a sitting or lying position.
- If you plan to have surgery than needs a general anesthetic, tell your doctor or dentist that you are taking this medicine.
- Tell your doctor or pharmacist immediately if you come pregnancy while taking NAUSETIL.

Call your doctor straight away 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 NAUSETIL.

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

Notice an unexplained fever, ridged muscles or altered consciousness.

These are symptoms of a rare condition called neuroleptic malignant syndrome. Your doctor may tell you to stop taking NAUSETIL.

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

Things you should not do

- Do not give NAUSETIL to children or adolescents under 18 years of age.
- Do not give NAUSETIL 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.

Driving or using machines

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

NAUSETIL may cause dizziness, light-headedness, tiredness and drowsiness in some people, especially in the first few days of treatment.

Drinking alcohol

Tell your doctor if you drink alcohol.

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 NAUSETIL.

Looking after your medicine

- 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.

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 about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• constipation• dry mouth• drowsiness• restlessness• trembling, rigid posture, mask-like face, slow movements and a shuffling unbalanced walk• twitching• blurred vision• agitation	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• dizziness, light-headedness• changes in heart beat• swelling of the hands, ankles or feet• swelling and redness along a vein which is extremely tender when touched, which may be a serious blood clot• 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• nasal stuffiness• excessive thirst• dry mouth and skin• eye problems such as changes in vision, changes in eye colour, uncontrolled eye movements or eye pain	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.

<p>If any of the following happen, go to Accident and Emergency at your nearest hospital:</p> <ul style="list-style-type: none"> • unusual muscle tone or • unusual muscle tone or spasms causing distortion of the body in children • chest pain and shortness of breath 	
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Who distributes NAUSETIL

Aspen Pharmacare Australia Pty Ltd
 34-36 Chandos St
 St Leonards NSW 2065
 Australia

This leaflet was prepared in December 2022

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

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.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What NAUSETIL contains

Active ingredient (main ingredient)	5 mg prochlorperazine maleate
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • wheat starch • calcium hydrogen phosphate • magnesium stearate • sodium lauryl sulfate • quinoline yellow
Potential allergens	gluten

Nausetil tablets do not contain sucrose or lactose.

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

What NAUSETIL looks like

NAUSETIL 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.

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