

NAUSRELIEF
CONSUMER MEDICINE INFORMATION

July 2011 / Version 2.5

NAUSRELIEF

Contains the active ingredient Prochlorperazine maleate

Consumer Medicine Information

What is in this leaflet?

This leaflet answers some common questions about **NAUSRELIEF**

It does not contain all the available information that is known about **NAUSRELIEF**.

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 using this medicine against the benefits he/she expects 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 NAUSRELIEF is used for

NAUSRELIEF contains prochlorperazine maleate. It belongs to a group of medicines called phenothiazines. It works by acting on specific receptors in the brain.

NAUSRELIEF is used to treat nausea associated with migraine (throbbing headache, usually affecting one side of the head and often accompanied by nausea, vomiting and sensitivity to light).

NAUSRELIEF is available in packs of 10 tablets from your pharmacist. Ask your doctor or pharmacist if you have any questions why **NAUSRELIEF** has been recommended for you.

Before you take NAUSRELIEF

When you must not take it

Do not take if you are under 18 years of age.

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NAUSRELIEF
CONSUMER MEDICINE INFORMATION

July 2011 / Version 2.5

Do not take NAUSRELIEF if you have an allergy to:

- Prochlorperazine
- The group of medicines called phenothiazines
- Any of the ingredients listed at the end of this leaflet

Symptoms of an allergic reaction to **NAUSRELIEF** may include:

- Shortness of breath, wheezing or difficulty in breathing
- Swelling of the face, lips, tongue or other parts of the body
- Rash, itching or hives on the skin

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

- Shock
- Disease of the blood with a low number of blood cells
- Yellowing of the skin and/or eye, also called jaundice

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

If you take this medicine after the expiry date has passed, it may not work as well.

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

If you are not sure whether you should take NAUSRELIEF, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to:

- Any other medicines
- Any other substances, such as foods, preservatives or dyes.

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

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

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

- Pheochromocytoma, a rare tumor 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.

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NAUSRELIEF
CONSUMER MEDICINE INFORMATION

July 2011 / Version 2.5

- Myasthenia gravis, a disease of the muscles causing drooping eyelids, double vision, difficulty in speaking and swallowing and sometimes muscle weakness in the arms
- Kidney problems
- Heart and blood vessel problems or a family history of these problems such as stroke, blood clots and low blood pressure
- Liver disease
- Prostate problems
- Epilepsy, seizures or fits
- Low blood calcium levels
- Thyroid problems.
- Glaucoma, a condition in which there is 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.

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

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 and **NAUSRELIEF** may interfere with each other. These include:

- Some medicines used to control depression or mood swings
- Alcohol
- Desferrioxamine, a medicine used when you have too much iron in your blood
- Procarbazine, an anticancer drug
- Some medicines used to control epilepsy
- Medicines used to treat high blood pressure and fluid build-up in your body
- Medicines to help you sleep
- Other medicines used to calm emotional and mental conditions
- Medicines used for Parkinson's disease such as levodopa;
- propranolol, a medicine used to control irregular heartbeat, high blood pressure or prevent migraine;
- anticholinergic medicines-includes some medicines used for stomach cramps or spasms, to prevent travel sickness, treat Parkinson's disease or incontinence

These medicines may be affected by **NAUSRELIEF** or may affect how well it works.

You may need different amounts of your medicine or may need to take different medicines.

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NAUSRELIEF
CONSUMER MEDICINE INFORMATION

July 2011 / Version 2.5

Your doctor will advise you.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while taking **NAUSRELIEF**.

How to take NAUSRELIEF

Follow all directions given by your doctor or pharmacist carefully.

How much to take

Adults 18 years of age and older

For the treatment of nausea, associated with migraine, take one or two tablets with water, two or three times a day if necessary or as advised by your pharmacist or doctor.

Do not use in children under 18 years of age.

How to take it

Swallow **NAUSRELIEF** tablets whole with a glass of water. Do not chew the tablets

If you take too much (overdose)

Do not try to vomit

Immediately telephone your doctor or pharmacist or the Poisons Information Centre (13 11 26) or go to Accident and Emergency at your nearest hospital if you think that you, or anyone else, has taken too much NAUSRELIEF. 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
-

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NAUSRELIEF
CONSUMER MEDICINE INFORMATION

July 2011 / Version 2.5

- Decrease in body temperature
- Small pupils in the eye
- Difficulty in swallowing or breathing
- Blue skin

While you are taking NAUSRELIEF

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 some people taking phenothiazine medicine, including **NAUSRELIEF**. This condition is more likely to occur during long term treatment with **NAUSRELIEF**, especially in elderly women.

Tell you doctor immediately or go to Accident and Emergency at the nearest hospital if you experience the following symptoms, which may be due to a serious reaction called Neuroleptic Malignant syndrome:

- sudden increase in body temperature
- stiff muscles
- fast heart beat
- altered mental state
- excessive sweating
- difficulty in breathing

Tell any other doctors, dentists and pharmacists who are treating you that you take NAUSRELIEF

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

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

Things you must not do

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

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NAUSRELIEF
CONSUMER MEDICINE INFORMATION

July 2011 / Version 2.5

Do not take NAUSRELIEF 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 NAUSRELIEF affects you.

NAUSRELIEF may cause dizziness, lightheadedness, tiredness, drowsiness in some people. Make sure you know how you react to NAUSRELIEF before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs do not drive. If you drink alcohol, dizziness or lightheadedness may be worse.

If NAUSRELIEF makes you feel light-headed, dizzy or faint, be careful when getting up from a sitting or lying position. Getting up slowly may help. Be careful when drinking alcohol while taking NAUSRELIEF.

Combining NAUSRELIEF and alcohol can make you more sleepy, dizzy or light-headed.

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

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

NAUSRELIEF 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 even severe sunburn. If your skin does appear to be burning, tell your doctor

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

NAUSRELIEF 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 NAUSRELIEF.

NAUSRELIEF 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.

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NAUSRELIEF
CONSUMER MEDICINE INFORMATION

July 2011 / Version 2.5

Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects. If you are over 65 years of age you may have an increased chance of getting side effects.

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

If you get any side effects, do not stop taking NAUSRELIEF without first talking to your doctor or pharmacist.

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

- Low blood pressure
- Changes in heart beats
- Swelling of the hands, ankles or feet
- 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, cramps and vomiting
- Difficulty passing urine
- Yellowing of the skin and/or eyes
- Headache
- Insomnia
- Seizures
- Difficulty in breathing

See “Things you must do” for more information on side effects.

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

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

You may not experience any of them.

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**NAUSRELIEF
CONSUMER MEDICINE INFORMATION**

July 2011 / Version 2.5

After taking NAUSRELIEF

Storage

Keep NAUSRELIEF tablets in a cool dry place where the temperature stays below 25°C. Protect from light.

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

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

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

Do not leave it in the car on hot days or on window sills.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one and-a-half meters above the ground is a good place to store medicines.

Disposal

If you stop taking NAUSRELIEF, or the medicine has passed its expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

NAUSRELIEF tablets are white, round and marked with "5". Tablets are available in a pack size of 10 tablets

Ingredients

NAUSRELIEF tablets contain:

Active Ingredient:

Prochlorperazine maleate 5mg

Inactive Ingredients:

lactose monohydrate, starch - maize, purified water, silica colloidal anhydrous, magnesium stearate.

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**NAUSRELIEF
CONSUMER MEDICINE INFORMATION**

July 2011 / Version 2.5

Manufacturer/Sponsor

IPCA PHARMA (AUSTRALIA) PTY. LTD

6 Morotai Avenue
Ashburton
VIC 3147, Australia

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