#### **Avomine**®

Promethazine theoclate 25 mg tablets 30 tablet pack

#### **Consumer Medicine Information**

#### What is in this leaflet

This leaflet answers some common questions about Avomine tablets.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist who have more detailed information.

All medicines have risks and benefits.

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

# Keep this leaflet with the medicine as you may want to read it again.

#### What Avomine is used for

Avomine belongs to a group of medicines called phenothiazines.

Avomine is used to prevent or treat motion sickness.

Avomine is also used to prevent or treat nausea (feeling sick) and vomiting associated with other causes including:

- other medicines
- radiation treatment
- migraine (severe headache)
- infectious diseases
- problems with balance

## Do not give Avomine to children 9 years of age or under.

#### Before you take Avomine

#### When you must not take it

Do not take Avomine if you have an allergy to Avomine or any of the ingredients listed at the end of the leaflet.

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

### Do not take Avomine after the expiry date printed on the pack.

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

Do not give Avomine to children 9 years of age or under.

#### Do not give Avomine to children or adolescents with signs or symptoms of Reye's Syndrome.

Symptoms include feeling sick, vomiting, tiredness, lack of energy, and indifference.

#### Tell your pharmacist or doctor if:

- you are pregnant or intend to become pregnant
- you are breastfeeding or plan to breastfeed
- you are allergic to any other medicines, foods, dyes or preservatives

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

- asthma, bronchitis or a persistent cough
- epilepsy, seizures or fits
- liver or kidney disease
- fast or irregular heart beat
- stomach problems
- difficulty passing urine

- glaucoma, a condition in which there is usually a build up of fluid in the eye
- severe heart disease, caused by poor blood flow in the blood vessels of the heart. The first symptom is usually angina or heart attack

#### Taking other medicines

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

#### Do not take Avomine if you are taking or being given any of the following medicines:

- Sedatives or hypnotics, medicines used to produce calmness or to help you sleep
- Anticholinergic agents, including medicines used to treat stomach cramps, travel sickness or Parkinson's Disease
- Antidepressants, medicines used to treat depression
- Other antihistamines, medicines used to prevent the symptoms of allergy (such as hay fever)
- Alcohol

These medicines may be affected by Avomine, or may affect how well it works. Your pharmacist or doctor will have more information on medicines to be careful with or avoid while taking Avomine.

# If you are not sure whether you should start taking Avomine, contact your pharmacist or doctor.

#### How to take Avomine

#### Adults

#### Prevention of travel sickness:

For long journeys swallow one tablet with water each night at bedtime, starting the night before travelling. For short journeys, swallow one tablet 1 to 2 hours before the start of the journey.

#### Treatment of travel sickness:

Swallow one tablet with water and then a second tablet the same evening. A third tablet should then be taken on the following evening. Additional tablets may be taken to prevent travel sickness or when they appear to be needed. It is rare to need to take more than 1 tablet in 8 hours. Do not take more than 4 tablets in 24 hours.

Nausea and vomiting due to other causes: Swallow one tablet with water as required. One tablet at bedtime is usually enough.

Do not take more than 4 tablets in 24 hours. Children:

Do not give Avomine to children 9 years of age or under.

Avomine Tablets may be crushed and then mixed with water before administering to children or any individual that has difficulty swallowing tablets.

Phenergan Elixir is more suitable for use in young children.

Children over 10 years of age:give the corresponding adult dose.

Do not take more than the recommended dose.

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

#### If you forget to take them

If you miss your dose and you do not feel sick take your next dose when you are meant to.

If you miss your dose, and you feel sick, take the missed dose as soon as possible, then go back to taking your Avomine tablets as you would normally. If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

#### What do I do in case of Overdose?

Immediately telephone your doctor or pharmacist or the Poisons Information Centre (telephone 13 11 26) or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using Avomine

#### Things you must do

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

#### Things you must not do

Do not give Avomine to anyone else, even if their symptoms seem to be the same as yours. Do not take Avomine to treat any other complaints unless your pharmacist or doctor tells you to.

#### Things to be careful of

Avomine may cause drowsiness in some people. Make sure you know how your react to Avomine before you drive a car, operate machinery, or do anything else that could be dangerous if you are drowsy. If this occurs do not drive or operate machinery.

Avoid alcohol while you are taking Avomine.

Tell your doctor if you need to take a pregnancy or skin allergy test. Avomine may interfere with the test results.

#### Side Effects

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

Like all other medicines, Avomine may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. Your pharmacist or doctor will be able to answer any questions you may have.

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

- tiredness, sleepiness
- anxiety, restlessness
- dizziness
- constipation or diarrhoea
- loss of appetite
- nausea or vomiting
- stomach upset
- dry mouth
- blurred vision

Tell your doctor immediately or go to accident and emergency at the nearest hospital if you notice any of the following:

• fast or irregular heart beat

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- tremors or convulsions
- swelling of the face, lips or tongue
- wheezing or trouble breathing
- skin rash or hives

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.

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.

#### After using Avomine

#### Storage

Keep your tablets in a cool, dry place where the temperature stays below  $30^\circ C.$ 

Do not store Avomine 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 your tablets in a safe place out of the

#### reach of children.

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

#### Disposal

If your pharmacist or doctor has told you to stop taking Avomine or it has passed the expiry date, ask your pharmacist what to do with any that are left over.

#### **Product Description**

#### What do Avomine tablets look like?

Avomine tablets are white, plain on one side and with a line on the other.

Avomine tablets are available in blister packs of 30 tablets.

## What are the ingredients in Avomine tablets?

Each tablet contains 25 mg of promethazine theoclate (the active ingredient), wheat starch, lactose, dextrin, talc and magnesium stearate.

Avomine contains lactose and gluten.

#### Manufacturer

Avomine is supplied in Australia by: sanofi-aventis australia pty ltd

12-24 Talavera Road Macquarie Park NSW 2113

Avomine is supplied in New Zealand by: sanofi-aventis new zealand limited Level 8, James & Wells Tower 56 Cawley Street Ellerslie, Auckland Avomine 25 mg tablets AUST R 27484 30 tablet Pack Date of Preparation: July 2009