# Stemetil®

## 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 Stemetil?

Stemetil contains the active ingredient prochlorperazine. Stemetil is used to treat nausea, vomiting and dizziness due to various causes, including migraine (severe headache). For more information, see Section 1. Why am I using Stemetil? in the full CMI.

## 2. What should I know before I use Stemetil?

Do not use if you have ever had an allergic reaction to prochlorperazine 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 Stemetil? in the full CMI.

## 3. What if I am taking other medicines?

Some medicines may interfere with Stemetil 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 Stemetil?

- For adults, the usual recommended dose for nausea and vomiting is 1 or 2 tablets two to three times daily. The usual recommended dose for dizziness is 1 or 2 tablets three to four times daily. If you are not able to take a tablet, then one 25mg suppository or a 1mL (12.5mg) injection is the recommended dose.

More instructions can be found in Section 4. How do I use Stemetil? in the full CMI.

## 5. What should I know while using Stemetil?

| | |
|---|---|
| **Things you should do** | • Remind any doctor, dentist or pharmacist you visit that you are using Stemetil.<br>• 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. |
| **Things you should not do** | • Do not stop using this medicine suddenly or reduce the dosage, even if you are feeling better, without checking with your doctor first.<br>• Do not take any medicines that cause drowsiness while you are taking Stemetil. |
| **Driving or using machines** | • Be careful before you drive or use any machines or tools until you know how Stemetil affects you.<br>• Stemetil may cause dizziness, light-headedness, tiredness, drowsiness in some people. |
| **Drinking alcohol** | • Tell your doctor if you drink alcohol.<br>• Be careful when drinking alcohol while taking Stemetil. |
| **Looking after your medicine** | • Keep Stemetil in a cool, dry place. Protect from light.<br>• Keep Stemetil where young children cannot reach it. |

For more information, see Section 5. What should I know while using Stemetil? in the full CMI.

## 6. Are there any side effects?

Less serious side effects include constipation, dry mouth, drowsiness, restlessness, trembling, rigid posture, mask-like face, slow movements and a shuffling unbalanced walk, uncontrollable twitching, jerking or writhing movements, blurred vision, and low blood pressure. Serious side effects include unusual muscle tone or spasms causing distortion of the body in children, a sudden increase in body temperature, extremely high blood pressure and severe convulsions, shortness of breath, wheezing, difficulty in breathing or swallowing, swelling of the face, lips, tongue or other parts of the body, and a rash, itching or hives on the skin. If you experience any of these serious side effects, go straight to the Emergency Department at your nearest hospital. 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.

# Stemetil®

**Active ingredient:** *prochlorperazine*

## Consumer Medicine Information (CMI)

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

**Where to find information in this leaflet:**


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


## 1. Why am I using Stemetil?

**Stemetil contains the active ingredient prochlorperazine.** Stemetil belongs to a group of medicines called phenothiazines.

It 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 (feeling sick) and vomiting.

**Stemetil is used to treat nausea, vomiting and dizziness due to various causes, including migraine (severe headache).**

Your doctor may have prescribed Stemetil for another reason. Ask your doctor if you have any questions about why Stemetil has been prescribed for you.

## 2. What should I know before I use Stemetil?

**Warnings**

**Do not use Stemetil if:**

- 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.
- 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

Stemetil is not recommended for use in children (under the age of 2 years or children under 10kg in weight) because children may develop unusual face and body movements.

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

**Check with your doctor if you:**

- you have allergies to any other medicines or any other substances, such as foods, preservatives or dyes.
- have any other medical conditions, especially the following:
  - phaechromocytoma, 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
  - bowel problems
  - epilepsy, seizures or fits
  - low blood calcium levels
  - decreased thyroid activity
  - 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
  - diabetes
  - a low number of white blood cells

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

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

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

It is recommended that you do not breastfeed while taking Stemetil, as it is not known whether Stemetil passes into breast milk.

## 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 Stemetil and affect how it works. These include:**

- some medicines used to control depression or mood swings or mental illness such as lithium
- medicines metabolised by CYP2D6 enzymes such as amitriptyline
- alcohol
- desferrioxamine, a drug used in iron overdose
- medicines used for cancer such as procarbazine
- some medicines used to control epilepsy such as phenobarbital and carbamazepine
- antibiotics used to treat infections
- medicines used to treat Parkinson's disease such as levodopa
- medicines used for the treatment of diabetes
- 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
- some oral medicines used to prevent your blood from clotting
- medicines used to treat high blood pressure or heart problems such as clonidine, guanethidine and propranolol
- medicines used to treat fluid build-up in your body
- medicines used to treat a fast or irregular heart beat e.g. amiodarone, quinidine, disopyramide.
- medicines that can slow your heart beat e.g. diltiazem, verapamil.
- medicines that can reduce potassium levels in the blood e.g. diuretics, laxatives.
- other medicines that can affect your heart rate e.g. methadone, pentamidine.
- antacids containing magnesium, aluminium and calcium salts, oxides and hydroxides
- adrenaline used for severe allergic reactions
- amfetamine

These medicines may be affected by Stemetil or may affect how well it works. You may need different amounts of your medicine or you may need to take different medicines. Your doctor will advise you.

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

## 4. How do I use Stemetil?

**How much to use**

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

**Adults' dose:**

- The usual recommended dose for nausea and vomiting is 1 or 2 tablets two to three times daily.
- The usual recommended dose for dizziness is 1 or 2 tablets three to four times daily.
- If you are not able to take a tablet, then one 25mg suppository or a 1mL (12.5mg) injection is the recommended dose.
- Follow the instructions provided and use Stemetil until your doctor tells you to stop.

**Children's dose:**

- The recommended dose for nausea, vomiting and dizziness is 1 tablet two to three times a day.
- Follow the instructions provided and use Stemetil until your doctor tells you to stop.

**When to use Stemetil**

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

**How to use Stemetil**

- **Tablets:**
- Swallow Stemetil tablets whole with a full glass of water.
- Do not chew the tablets.
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- **Suppository:**

1. Stemetil may be given as a suppository. First wash your hands well with soap and water, then follow these instructions: Go to the toilet and empty your bowels if possible. Do not strain.
2. Feel the suppository through its plastic shell. If it feels very soft, chill it in the fridge or cool it by holding it under cold water for several minutes.
3. Remove the suppository from its shell.
4. Moisten the suppository by dipping it briefly in cool water.
5. Put one foot up on the side of the bath or toilet, raising the knee to the chest.
6. Insert the suppository, pointed end first, gently into the rectum (back passage).
7. Try not to go to the toilet for at least one hour to allow the suppository to work.

If you are not sure what to do, ask your doctor or pharmacist.

- If you have trouble remembering to take your medicine,
- ask your pharmacist for some hints.

- **Injection:**
- Stemetil may be given as an injection into a muscle.
- Stemetil injection should only be given by a doctor, nurse or other trained person.

**If you use too much Stemetil**

If you think that you have used too much Stemetil, you may need urgent medical attention.

**Do not try to vomit.**

**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.** Your doctor or pharmacist has information on how to recognise and treat an overdose. Ask your doctor or pharmacist if you have any concerns.

## 5. What should I know while using Stemetil?

**Things you should do**

- Tell any other doctors, dentists and pharmacists who are treating you that you are taking Stemetil.
- If you are about to be started on any new medicines, tell your doctor, dentist or pharmacist that you are taking Stemetil.

- If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking Stemetil.
- If Stemetil makes you feel light-headed, dizzy or faint, be careful when getting up from a sitting or lying position. Getting up slowly may help.

**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 Stemetil. The condition is more likely to occur during long term treatment with Stemetil, especially in elderly women. In very rare cases, this may be permanent.
- become pregnant while taking Stemetil.

**Things you should not do**

- Do not give Stemetil to anyone else, even if they have the same condition as you.
- Do not take Stemetil to treat any other complaints unless your doctor or pharmacist tells you to.
- Do not stop taking Stemetil, or lower the dosage, even if you are feeling better, without checking with your doctor.
- Do not stop taking Stemetil suddenly. If you do, 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 Stemetil you take each day before stopping completely.
- Do not take any medicines that cause drowsiness while you are taking Stemetil.

**Sun exposure**

- Stemetil may cause your skin to be much more sensitive to sunlight than it is normally. It is advised to avoid exposure to direct sunlight during treatment.
- If outdoors, wear protective clothing and use at least a 15+ sunscreen.
- Exposure to sunlight may cause a skin rash, itching, redness, or 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. Stemetil may affect the way your body reacts to temperature changes.

**Driving or using machines**

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

As with other medicines, Stemetil may cause dizziness, light-headedness, tiredness, drowsiness in some people. If this occurs do not drive.

**Drinking alcohol**

**Tell your doctor if you drink alcohol.**

Be careful when drinking alcohol while taking Stemetil.

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

Your doctor may suggest you avoid alcohol while you are being treated with Stemetil.

**Looking after your medicine**

- Stemetil ampoules for injection should be stored at a pharmacy or hospital. The injection should be kept below 25°C and protected from light.
- Keep Stemetil suppositories in a cool dry place where the temperature stays below 25°C. Protect from light. Keep you Stemetil in the pack until it is time to use it. If you take the suppositories out of the pack, they may not keep well.
- Keep Stemetil tablets in a cool dry place where the temperature stays below 30°C. Protect from light. Keep your Stemetil in the pack until it is time to take them. If you take the tablets out of the pack, they may not keep well.

Store your Stemetil suppositories or tablets 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.

## 6. Are there any side effects?

All medicines can have side effects. Stemetil helps most people with nausea, vomiting and dizziness, but it may have unwanted side effects in a few people. If you are over 65 years or age you may have an increased chance of getting side effects.

If you do experience any side effects, do not stop taking Stemetil without first talking to your doctor or pharmacist. Most side effects 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 |
|---|---|
| **Gastrointestinal or gut related:**<br>• constipation<br>• dry mouth<br>•<br>• **Central nervous system related:**<br>• drowsiness<br>• restlessness<br>• trembling, rigid posture, mask-like face, slow movements and a shuffling unbalanced walk<br>• uncontrollable twitching, jerking or writhing movements<br>•<br>• **Vision or eye related:**<br>• blurred vision<br>•<br>• **Cardiovascular or heart related:**<br>• low blood pressure | **Speak to your doctor if you have any of these less serious side effects and they worry you.** |

| Less serious side effects | What to do |
|---|---|
| **The following side effects are less common:**<br>• changes in heart beats<br>• swelling of the hands, ankles or feet<br>• skin rash<br>• for females: unusual secretion of breast milk, irregular or stopping of periods<br>• for males: breast enlargement, difficulty in ejaculating, getting or maintaining an erection, or persistent painful erection<br>• severe pain in the stomach with bloating, cramps and vomiting<br>• difficulty passing urine<br>• yellowing of the skin and/or eyes<br>• headache<br>• insomnia<br>• seizures<br>• agitation<br>• dizziness<br>• difficulty in breathing<br>• brownish deposits in the eyes<br>• stuffy nose | |

**Serious side effects**

| Serious side effects | What to do |
|---|---|
| **Allergic reaction related:**<br>• shortness of breath, wheezing or difficulty in breathing or swallowing<br>• swelling of the face, lips, tongue or other parts of the body<br>• rash, itching or hives on the skin<br>**Musculoskeletal related:**<br>• unusual muscle tone or spasms causing distortion of the body in children<br>**Other:**<br>• sudden increase in body temperature, extremely high blood pressure and severe convulsions. | **Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these side effects. These are very serious side effects. You may need urgent medical attention or hospitalisation.** |

**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 Stemetil tablets contain**

| | |
|---|---|
| **Active ingredient (main ingredient)** | prochlorperazine maleate 5mg |
| **Other ingredients (inactive ingredients)** | wheat starch<br>calcium hydrogen phosphate dihydrate<br>magnesium stearate<br>sodium lauryl sulfate |

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

**What Stemetil suppositories contain**

| | |
|---|---|
| **Active ingredient (main ingredient)** | prochlorperazine base equivalent to 25mg prochlorperazine maleate |
| **Other ingredients (inactive ingredients)** | suppository base (saturated vegetable fat) |

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

**What Stemetil injections contain**

| | |
|---|---|
| **Active ingredient (main ingredient)** | prochlorperazine mesilate 12.5 mg/mL |
| **Other ingredients (inactive ingredients)** | sodium chloride<br>sodium sulfite<br>sodium metabisulfite<br>monoethanolamine<br>water for injection |
| **Potential allergens** | Sodium sulfite, sodium metabisulfite (sulfites) |

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

**What Stemetil looks like**

Stemetil tablets are white, round and marked with "S". Tablets are available in packs of 25 (AUST R 27564).

Stemetil suppositories are cream, smooth, torpedo shaped and are available in packs of 5 (AUST R 27557).

Stemetil for injection is a clear liquid in a 1mL glass ampoule, in a pack of 10 ampoules (AUST R 27555).

**Who distributes Stemetil**

Stemetil is supplied in Australia by:

sanofi-aventis australia pty ltd

12-24 Talavera Road

Macquarie Park NSW 2113

Toll Free Number (medical information): 1800 818 806

Email: medinfo.australia@sanofi.com

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