SIMPRAL®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking SIMPRAL?

SIMPRAL contains the active ingredient pramipexole dihydrochloride monohydrate. SIMPRAL is used to treat the symptoms of Parkinson's disease and Restless Legs Syndrome (RLS).

For more information, see Section 1. Why am I taking SIMPRAL? in the full CMI.

2. What should I know before I take SIMPRAL?

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

3. What if I am taking other medicines?

Some medicines may interfere with SIMPRAL 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 take SIMPRAL?

The dose you should take and how often you take it, will depend on the condition that you are being treated for.

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

5. What should I know while taking SIMPRAL?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are taking SIMPRAL. • Tell your doctor as soon as possible if there is any worsening of your condition or if you feel that SIMPRAL is not helping your condition. • Tell your doctor if, you have not used SIMPRAL exactly as prescribed. • Be careful getting up from a sitting or lying position. • Monitor your skin and see your doctor in case of any concerns.
Things you should not do	• Do not give your medicine to anyone else, even if they have the same condition as you. • Do not stop taking your medicine or change the dosage without checking with your doctor. • Do not give this medicine to a child or adolescent under the age of 18 years.
Driving or using machines	• Be careful driving or operating machinery until you know how SIMPRAL affects you.
Drinking alcohol	• Be careful when drinking alcohol while you are taking this medicine. Combining SIMPRAL and alcohol can make you more drowsy or sleepy.
Looking after your medicine	• Store below 25°C. • Keep it where young children cannot reach it.

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

6. Are there any side effects?

Tell your doctor immediately if you or your family notice any of the following side effects: memory loss, fainting, signs of allergy such as skin rash; swelling of the face, lips, tongue or other body parts; difficulty breathing; excessive sleepiness; compulsive behaviour such as gambling, hypersexuality, shopping, medication use and repetitive, purposeless activities; severe suspiciousness; shortness of breath or tightness in the chest; swelling of the feet or legs.

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.

SIMPRAL®

Active ingredient(s): *pramipexole dihydrochloride monohydrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking SIMPRAL. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking SIMPRAL.**

Where to find information in this leaflet:

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

1. Why am I taking SIMPRAL?

SIMPRAL contains the active ingredient pramipexole dihydrochloride monohydrate. SIMPRAL belongs to a group of medicines known as "dopamine agonists", which bind to dopamine receptors. It is believed that SIMPRAL works by having a similar effect as dopamine in the brain which may help in conditions where there is not enough dopamine produced or dopamine signalling in the brain.

SIMPRAL is used to treat symptoms of:

- PARKINSON'S DISEASE
  - Parkinson's disease is a disease of the brain that affects body movement.
  - The symptoms of Parkinson's disease are caused by a lack of dopamine, a naturally occurring chemical produced by certain brain cells.
  - Dopamine relays messages in the part of the brain that controls movement. When too little dopamine is produced, this results in Parkinson's disease.
- RESTLESS LEGS SYNDROME (RLS)
  - RLS is a neurological disorder in which there is an overwhelming urge to move the legs to stop unpleasant sensations.
  - The sensations vary from person to person and range from uncomfortable to irritating to painful. The symptoms usually occur when sitting or lying down - which often leads to problems falling or staying asleep. Sometimes the arms and body may be affected. Current evidence suggests that RLS may be due to faulty dopamine signals in certain areas of the brain.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed it for another reason. This medicine is available only with a doctor's prescription.

SIMPRAL is not addictive.

2. What should I know before I take SIMPRAL?

Warnings

Do not take SIMPRAL:

- if you are allergic to pramipexole dihydrochloride monohydrate, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can take this medicine. Some of the symptoms of an allergic reaction may include:
  - shortness of breath, wheezing or difficulty breathing
  - swelling of the face, lips, tongue or other parts of the body
  - rash, itching or hives on the skin

Check with your doctor if you:

- are not sure whether you should start taking this medicine
- have allergies to any other medicines, foods, preservatives or dyes.
- have or have had any of the following medical conditions:
  - kidney problems
  - mental illnesses
  - low blood pressure
  - trouble controlling your muscles (dyskinesia).
- take any medicines for any other condition.

If you have not told your doctor about any of the above, tell him/her before you start taking SIMPRAL.

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. Your doctor can discuss with you the risks and benefits involved.

Talk to your doctor if you are breastfeeding or intend to breastfeed. SIMPRAL is not recommended during breastfeeding, as it may pass into breast milk and there is a possibility that your baby may be affected.

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 and SIMPRAL may interfere with each other. These include:

- levodopa, levodopa/carbidopa combination, or other medicines used to treat Parkinson's disease (e.g. amantadine)
- medicines used in the treatment of high blood pressure or heart problems (e.g. digoxin, diltiazem, procainamide, quinidine, triamterene, verapamil, hydrochlorothiazide)
- medicines used in the treatment of mental illness/ psychosis (antipsychotics or neuroleptics)
- metoclopramide, a medicine commonly used to help treat nausea and vomiting
- cimetidine or ranitidine, medicines used to treat stomach ulcer or duodenal ulcers
- quinine, a medicine used to treat malaria
- some antibiotics (e.g. trimethoprim, cephalosporins, penicillins)
- indometacin, a medicine used to treat arthritis
- chlorpropamide, a medicine used to treat diabetes
- other medicines that can cause drowsiness or sleepiness (e.g. antihistamine or some cough and cold preparations).

These medicines may be affected by SIMPRAL or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

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

4. How do I take SIMPRAL?

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet.

SIMPRAL is available in a number of tablet strengths. Your doctor or pharmacist will tell you how many tablets you will need to take each day. This depends on your condition and whether or not you are taking any other medicines.

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

How much to take

The dose varies from patient to patient. Your doctor may first start you on a low dose of SIMPRAL and slowly increase the amount of SIMPRAL until the right dose is reached to control your condition.

PARKINSON'S DISEASE

- The usual starting dose is one SIMPRAL 0.125 mg tablet three times a day.
- Depending on how you respond to the treatment, your doctor may increase your daily dose gradually in steps of 0.75 mg at weekly intervals until the right dose for your needs is reached. The maximum dose is 4.5 mg of SIMPRAL per day.

RESTLESS LEGS SYNDROME

- The usual starting dose is one SIMPRAL 0.125 mg tablet once a day, usually 2 to 3 hours before you go to bed.
- Depending on how you respond to the treatment, your doctor may increase your dose gradually every 4 to 7 days until the right dose for your needs is reached. The maximum dose is 0.75 mg of SIMPRAL per day.

If you have stopped taking your medicine for more than a few days, speak with your doctor before you restart your medication.

Follow the instructions provided by your doctor or pharmacist carefully.

When to take SIMPRAL

- SIMPRAL should be taken at about the same time each day.
- Taking it at the same time each day will have the best effect. It will also help you remember when to take it.
- It does not matter if you take this medicine before or after food.

How to take SIMPRAL

Swallow the tablets whole with a full glass of water.

How long to take it

Continue taking your medicine for as long as your doctor tells you to.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take SIMPRAL

PARKINSON'S DISEASE

- If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.
- Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.
- Do not take a double dose to make up for the dose you missed.
- This may increase the chance of you getting an unwanted side effect.

RESTLESS LEGS SYNDROME

- If you forget to take SIMPRAL before you go to bed and you wake up late in the night or early morning, do not take any SIMPRAL as you may have trouble waking in the morning.
- Skip the dose you missed and take the next dose when you are meant to.

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.

If you take too much SIMPRAL

If you think that you have taken too much SIMPRAL, you may need urgent medical attention.

Symptoms of an overdose may include nausea, vomiting, abnormal uncontrolled movements, hallucinations, agitation and dizziness or light-headedness.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, 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.

5. What should I know while taking SIMPRAL?

Things you should do

Tell all doctors and pharmacists who are treating you that you are taking SIMPRAL.

Be careful getting up from a sitting or lying position.

You may feel dizzy or lightheaded while taking SIMPRAL, especially during the first few weeks of treatment. If you wish to stand up, you should do so slowly.

You should monitor your skin and see your doctor in case of any concerns.

Patients with Parkinson's disease may have an increased risk of developing melanoma.

Tell your doctor as soon as possible if there is any worsening of your condition.

Some people taking SIMPRAL for treatment of Restless Legs Syndrome may experience more intense, spreading, or worsening symptoms.

Tell your doctor if, for any reason, you have not taken SIMPRAL exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

You may feel a craving to take more SIMPRAL than what your doctor has prescribed. This is called Dopamine Dysregulation Syndrome (DDS) and can lead you to taking too much SIMPRAL. This could increase your risk of experiencing side effects. If you feel the desire to take more SIMPRAL than you are prescribed, talk to your doctor or pharmacist.

If you or your family notices an increase in compulsive behaviour, seek immediate medical advice.

Tell your doctor if you experience symptoms such as depression, apathy, anxiety, fatigue, sweating or pain after stopping or reducing your SIMPRAL treatment. If the problems persist for more than a few weeks, your doctor may need to adjust your treatment.

Tell your doctor if you develop an inability to keep your body and neck straight and upright. For example, you may experience abnormal posture such as forward bending of the head and neck, forward bending of the lower back or sidewards bending of the back.

Call your doctor straight away if:

- there is any worsening of your condition.

Some people taking SIMPRAL for treatment of Restless Legs Syndrome may experience earlier onset of symptoms (in the evening or even in the afternoon), increase in symptoms and spreading of symptoms to other limbs.

Things you should not do

Do not stop taking this medicine suddenly, unless advised to do so by your doctor.

- If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects.
- If you are taking SIMPRAL for your Parkinson's Disease and your doctor asks you to stop taking SIMPRAL, the dose will normally be reduced gradually over several days.

Do not take SIMPRAL to treat any other complaints unless your doctor tells you to.

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

Do not stop taking your medicine or change the dosage without checking with your doctor.

Do not give this medicine to a child or adolescent under the age of 18 years. Safety and effectiveness in children younger than 18 years have not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

Driving or using machines

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

SIMPRAL may cause drowsiness, hallucinations and episodes of sudden onset of sleep in some people.

Make sure you know how you react to Sifrol before you engage in any activities where impaired alertness may put yourself or others at risk of serious injury.

If you experience excessive drowsiness or an episode of sudden onset of sleep (while performing daily activities), do not drive or perform any potentially dangerous activities, and contact your doctor.

Drinking alcohol

Be careful when drinking alcohol while taking SIMPRAL.

Combining SIMPRAL and alcohol can make you more drowsy or sleepy.

Looking after your medicine

- Keep your tablets in the pack until it is time to take them. If you take the tablets out of the pack they may not keep well.

- Keep your tablets in a cool dry place where the temperature stays below 25°C. Heat and dampness can destroy some medicines.
- A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

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 your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

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 SIMPRAL.

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.

Do not be alarmed by the following list of side effects. You may not experience any of them.

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
Digestive system: • feeling sick (nausea) • constipation • dry mouth • vomiting • diarrhoea **Metabolic & nutritional system:** • swelling of hands, ankles or feet (peripheral oedema) • weight gain or loss **Nervous system:** • dizziness • drowsiness • difficulty sleeping or unusual dreams • loss or gain of sexual drive • uncontrolled twitching, jerking or writhing movements (dyskinesia) • tiredness • restlessness • headache • forward bending of the head and neck	**Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.** **Some of these side effects are more common at the start of treatment and lessen or disappear with time.**
Others: • light-headedness on standing up, especially when getting up from a sitting or lying position (hypotension) • blurred vision	

Serious side effects

Serious side effects	What to do
Nervous system: • loss of memory (amnesia) • fainting • excessive sleepiness or sudden onset of sleep during normal daily activities • compulsive behaviour such as gambling, hypersexuality, shopping, eating, medication use and repetitive purposeless activities **Others:** • signs of allergy such as rash or hives on the skin; swelling of the face, lips, tongue or other parts of the body; wheezing or difficulty breathing • confusion or hallucinations (seeing, feeling or hearing things that are not there) • mental illness causing severe suspiciousness (paranoia) • shortness of breath or tightness in the chest (dyspnoea) • swelling of the feet or legs due to fluid build-up (heart failure)	**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.** **These 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 SIMPRAL contains

Active ingredient (main ingredient)	pramipexole dihydrochloride monohydrate
Other ingredients (inactive ingredients)	• mannitol • pregelatinised maize starch • hyprolose • crospovidone • sodium citrate • colloidal anhydrous silica • magnesium stearate

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

What SIMPRAL looks like

SIMPRAL 0.125 mg is a white to off-white, round, flat-faced tablet, debossed with "PX1" on one side and "M" on the other side (AUST R 173139).

SIMPRAL 0. 25 mg is a white to off-white, biconvex oval shaped tablet, debossed with "PX2" on one side and "M" on one side of breakline on other side (AUST R 173138).

SIMPRAL 1 mg is a white to off-white, round, flat-faced tablet, debossed with "M" over "PX4" on one side and breakline on the other side (AUST R 173137).

Who distributes SIMPRAL

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

This leaflet was prepared in October 2025.

SIMPRAL® is a Viatris company trade mark

SIMPRAL_cmi\Oct25/00