

SIMPRAL

pramipexole dihydrochloride monohydrate

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about SIMPRAL.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking SIMPRAL against the benefits expected for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What SIMPRAL is used for

SIMPRAL is used to treat the 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.

SIMPRAL works by having a similar effect as dopamine in the brain.

How SIMPRAL works

SIMPRAL contains the active ingredient pramipexole dihydrochloride monohydrate.

Pramipexole dihydrochloride monohydrate belongs to a group of medicines known as "dopamine agonists", which bind to dopamine receptors.

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.

SIMPRAL is not addictive.

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

SIMPRAL is not recommended for use in children under 18 years of age as its safety and effectiveness in that age group have not been established.

Before you take SIMPRAL

When you must not take it

Do not take SIMPRAL if you have an allergy to:

- any medicine containing pramipexole dihydrochloride monohydrate (active ingredient) or
- any of the ingredients listed at the end of this leaflet

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

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.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- kidney problems
- mental illnesses
- low blood pressure
- trouble controlling your muscles (dyskinesia).

Tell your doctor if you are pregnant or likely to become pregnant during your course of medication.

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

Tell your doctor if you are breastfeeding, or likely to breastfeed during your course of medication.

SIMPRAL is not recommended during breastfeeding, as it may pass into breast milk.

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

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from a 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 control 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.

How to take SIMPRAL

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

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 usual dose is one tablet a day.

Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.

Follow all directions given to you by your doctor or pharmacist carefully.

How to take it

Swallow the tablets whole with a full glass of water.

When to take it

Take your medicine 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 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 it

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.

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 (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much SIMPRAL. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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

While you are taking SIMPRAL

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking SIMPRAL.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you feel that SIMPRAL is not helping your condition, tell your doctor or pharmacist.

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

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

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

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 sideways bending of the back

Things you must not do

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.

It is important not to suddenly stop taking your SIMPRAL tablets, unless advised to do so by your doctor, since your condition may worsen.

If your doctor asks you to stop taking SIMPRAL, the dose will normally need to be reduced gradually over several days.

Things to be careful of

Be careful driving or operating machinery until you know how SIMPRAL affects you.

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

Make sure you know how you react to SIMPRAL 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.

Be careful when drinking alcohol while you are taking this medicine.

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

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.

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

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

Side effects

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

SIMPRAL helps most people with Parkinson's disease, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by the following list of side effects.

You may not experience any of them.

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

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

- feeling sick (nausea)
- vomiting
- constipation
- diarrhoea
- dry mouth
- drowsiness
- tiredness
- confusion or hallucinations (seeing, feeling or hearing things that are not there)
- restlessness

- dizziness
- headache
- light-headedness on standing up, especially when getting up from a sitting or lying position (hypotension)
- blurred vision
- swelling of hands, ankles or feet (peripheral oedema)
- uncontrolled twitching, jerking or writhing movements (dyskinesia)
- difficulty sleeping or unusual dreams
- weight gain or loss
- loss or gain of sexual drive.
- forward bending of the head and neck.

Some of these side effects are more common at the start of treatment and lessen or disappear with time.

Tell your doctor immediately if you or your family notice any of the following side effects:

- loss of memory (amnesia)
- fainting

- 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
- 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
- mental illness causing severe suspiciousness (paranoia)
- shortness of breath or tightness in the chest (dyspnoea)
- shortness of breath, swelling of the feet or legs due to fluid build-up (heart failure).

These are serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After taking SIMPRAL

Storage

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 25C.

Do not store SIMPRAL or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

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

Disposal

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.

Product description

What it 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.

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.

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.

Ingredients

SIMPRAL contains 0.125mg, 0.25mg or 1mg of pramipexole dihydrochloride monohydrate as the active ingredient.

It also contains the following inactive ingredients:

- mannitol
- pregelatinised maize starch
- hypolose
- crospovidone
- sodium citrate
- colloidal anhydrous silica
- magnesium stearate

This medicine does not contain lactose, sucrose, tartrazine or any other azo dyes.

Supplier

SIMPRAL is supplied in Australia by:

Alphapharm Pty Limited

Level 1, 30 The Bond

30 - 34 Hickson Road

Millers Point NSW 2000

www.mylan.com.au

Australian registration numbers:

SIMPRAL 0.125 mg:

AUST R 173139

SIMPRAL 0.25 mg:

AUST R 173138

SIMPRAL 1 mg:

AUST R 173137

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