

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 SIMIPEX?

SIMIPEX contains the active ingredient Pramipexole dihydrochloride monohydrate .

SIMIPEX is used used in the treatment of Parkinson's disease and Restless Legs Syndrome (RLS).

For more information, see Section [1. Why am I using SIMIPEX?](#) in the full CMI.

2. What should I know before I use SIMIPEX?

Do not use if you have ever had an allergic reaction to SIMIPEX (pramipexole), 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 SIMIPEX?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with SIMIPEX and affect how it works. 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.

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 SIMIPEX?

- For Parkinson's disease, SIMIPEX 0.125mg tablet should be taken in three times per day. Your daily dose will be increase every week by your doctor until a suitable daily dose is reached.
- For Restless Legs Syndrome, the usual starting dose is one SIMIPEX 0.125mg tablet once a day, 2 to 3 hours before you go to bed. Your doctor may increase your dose every 4 to 7 days if needed.
- SIMIPEX tablets should be swallowed whole with a glass of water. SIMIPEX can be taken with or without food.
- More instructions can be found in Section [4. How do I use SIMIPEX?](#) in the full CMI.

5. What should I know while using SIMIPEX?

Things you should do	<ul style="list-style-type: none">• Tell your doctor if you become pregnant while taking SIMIPEX. Special care is recommended during pregnancy. The benefits of SIMIPEX must be assessed against the possible effects on your unborn child.
Things you should not do	<ul style="list-style-type: none">• Do not take SIMIPEX to treat any other complaint unless your doctor says so.• Do not give this medicine to anyone else, even if their symptoms are similar to yours.
Driving or using machines	<ul style="list-style-type: none">• SIMIPEX may cause drowsiness, hallucinations and episodes of sudden onset of sleep, in some people. If affected, do not drive or operate machinery.
Looking after your medicine	<ul style="list-style-type: none">• Keep SIMIPEX Tablets in a cool dry and dark place where the temperature is below 30°C. Keep tablets in the packet until used, to protect from light.

For more information, see Section [5. What should I know while using SIMIPEX?](#) in the full CMI.

6. Are there any side effects?

- There are a number of side effects associated with this medicine. It is important to be aware of them so that you can identify any symptoms if they occur (see the full CMI for more details). The serious side effects are: loss of memory, 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. shortness of breath, swelling of the feet or legs due to fluid build-up (heart failure)

SIMIPEX Tablets

Active ingredient(s): *Pramipexole dihydrochloride monohydrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using SIMIPEX tablets. It does not contain all the available information. 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 taking SIMIPEX against the benefits this medicine is expected to have for you.

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 SIMIPEX.

Keep this leaflet with your medicine. You may need to read it again.

Where to find information in this leaflet:

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

1. Why am I using SIMIPEX?

SIMIPEX contains the active ingredient Pramipexole dihydrochloride monohydrate. It belongs to a group of medicines known as "dopamine agonists", which bind to dopamine receptors. It is believed that SIMIPEX works by having a similar effect as dopamine in the brain.

SIMIPEX is used in the treatment of Parkinson's disease and Restless Legs Syndrome (RLS).

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

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 sensation 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 sleep. 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. Your doctor may have prescribed SIMIPEX for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

SIMIPEX is not addictive.

2. SIMIPEX IS NOT ADDICTIVE. What should I know before I use SIMIPEX?

Warnings

Do not use SIMIPEX if:

- you are allergic to any medicine containing pramipexole or other or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

If you are not sure if you have these allergies, you should raise those concerns with your doctor.

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 use SIMIPEX if the packaging is torn or shows signs of tampering. Do not use SIMIPEX beyond the expiry date printed on the pack. Return it to your pharmacist for disposal.

Check with your doctor or pharmacist if you:

- you are not sure whether you should start taking this medicine.

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

It is essential that your doctor knows your medical history before prescribing SIMIPEX. Before taking this medicine. You must tell your doctor if you have, or have had, any of the following conditions:

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

If you are not sure if you have, or have had, any of these conditions, you should raise those concerns with your doctor.

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

Your doctor will advise you whether or not to take SIMIPEX or if you need to adjust the dose or adapt your treatment.

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. Special care is recommended during pregnancy. The benefits of SIMIPEX must be assessed against the possible effects on your unborn child.

SIMIPEX is not recommended during breastfeeding.

Talk to your doctor if you are breastfeeding or intend to breastfeed during your course of medication. In animal studies, SIMIPEX was shown to pass into breast milk, and can stop the production of milk

Use in Children

The use of SIMIPEX is not recommended in child or adolescent below 18 years of age.

Safety and effectiveness in children younger than 18 years have not been established.

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 SIMIPEX and affect how it works.

In particular, you should tell your doctor if you are taking:

Some medicines and SIMIPEX 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)
- certain medicines used in the treatment of mental illness/psychosis
- metoclopramide - commonly used to help control nausea and vomiting
- cimetidine or ranitidine - used to treat stomach or duodenal ulcer or reflux

- quinine - 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 SIMIPEX or may affect how well it works. You may need different amounts of the medicine, or you may need to take different medicines. Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

4. How do I use SIMIPEX?

How much to take

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

The tablets should be swallowed whole with a glass of water. SIMIPEX can be taken with or without food.

Parkinson's disease

The recommended initial dose for adults is one SIMIPEX 0.125 mg tablet three times per day. Your daily dose will be increased every week by your doctor until a suitable daily dose is reached.

The maximum recommended daily dose for SIMIPEX is 4.5 mg pramipexole dihydrochloride monohydrate.

Restless Legs Syndrome

The usual starting dose is one SIMIPEX 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 SIMIPEX per day

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

Ask your doctor for more information if you have been advised to take a different dose to that referred to above.

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

When to take / use SIMIPEX

Take SIMIPEX 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

How to take SIMIPEX?

It is important to take your SIMIPEX tablets as directed by your doctor.

A number of tablet strengths are available (see Product description). Make sure that you only take the tablet strength that your doctor has prescribed.

Your doctor may reduce your daily dose if you have another medical condition such as a kidney problem, or if you are currently taking other medicines.

How long to take it

Continue taking SIMIPEX for as long as your doctor tells you. 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 use SIMIPEX

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, then go back to taking it as you would normally.

Do not try to make up for missed doses by taking more than one dose at a time. This may increase the chance of you getting an unwanted side effect.

RESTLESS LEGS SYNDROME

If you forget to take SIMIPEX before you go to bed and you wake up late in the night or early morning, do not take any SIMIPEX as you may have trouble walking in the morning.

Skip the dose you missed and take the next dose when you are meant to.

If you have missed more than one dose, or are not sure what to do, check with your doctor or pharmacist.

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

If you use too much SIMIPEX

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

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. You may need urgent medical attention.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

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

5. What should I know while using SIMIPEX?

Things you should do

Always follow your doctor's instructions carefully.

Tell your doctor if you become pregnant while taking SIMIPEX.

If you are about to start taking a new medicine, tell your doctor and pharmacist that you are taking SIMIPEX.

Do not stop taking SIMIPEX or change the dose without checking with your doctor. It is important not to suddenly stop taking your SIMIPEX tablets, unless advised to do so by your doctor, since your condition may worsen or you may have unwanted side effects.

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

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

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

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

Seek immediate medical advice if you or your family notices an increase in compulsive behaviour.

Tell your doctor if you experience symptoms such as depression, apathy, anxiety, fatigue, sweating, or pain after stopping or reducing your SIMIPEX treatment. If the problems persist 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 should not do

- Do not take SIMIPEX to treat any other complaints unless your doctor tells you to.
- Do not give this medicine to anyone else, even if they have the same condition as you

Driving or using machines

Do not drive a car, operate machinery, or do anything else that could be dangerous (after taking SIMIPEX) until you know how the medicine affects you.

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

Make sure you know how you react to it 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.

Effects of food

Tablets should be taken with or without food

Drinking alcohol

Tell your doctor if you drink alcohol.

Be careful when drinking alcohol while taking SIMIPEX. Combining it 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 SIMIPEX, 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.

Looking after your medicine

- Keep SIMIPEX Tablets in the original pack until it is time to take them.
- Keep SIMIPEX Tablets in a cool dry and dark place where the temperature is below 30°C. Keep tablets in the packet until used, to protect from light.

Do not store your SIMIPEX in direct sunlight or heat. For example, do not leave your SIMIPEX in the car on hot days.

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

Do not leave medicines in the car or on window sills. Heat and dampness can destroy some medicines.

Keep your medicines where children cannot reach them. A locked cupboard at least one-and-a-half metres (1.5 m) above the ground is a good place to store medicines.

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.

Do not use this medicine after the expiry date.

6. Are there any side effects?

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.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions.

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

SIMIPEX 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 this list of possible side effects. You may not experience any of them.**

You should be aware that all prescription medicines carry some risks and that all possible risks may not be known at this stage despite thorough testing.

Your doctor has weighed the risks of your taking SIMIPEX against the expected benefits.

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

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • 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) • uncontrollable twitching, jerking or withering movements • difficulty sleeping or unusual dreams • weight gain or loss • loss or gain of sexual drive. • Forward bending of the head and neck. 	<p>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.</p>

In patients also taking other medicines to treat Parkinson's disease, abnormal uncontrolled movements can occur.

These side effects tend to appear at the start of treatment and lessen or disappear with time.

Sudden onset of sleep episodes (while engaged in daily activities) have been reported with/without prior warning signs, such as excessive drowsiness.

Compulsive behaviour have been reported in patients taking dopamine agonists for the treatment of Parkinson's disease, especially at high doses.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• loss of memory• 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.• shortness of breath, swelling of the feet or legs due to fluid build-up (heart failure)	<p>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.</p>

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 available with a doctor's prescription.

What SIMIPEX contains

Active ingredient (main ingredient)	pramipexole dihydrochloride monohydrate
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Other ingredients (inactive ingredients)	<p>SIMIPEX tablets contain:</p> <ul style="list-style-type: none">• mannitol• pregelatinised maize starch• microcrystalline cellulose• povidone• purified talc• magnesium stearate <p>Each SIMIPEX 0.125 mg tablet contains pramipexole dihydrochloride monohydrate 0.125 mg.</p> <p>Each SIMIPEX 0.25 mg tablet contains pramipexole dihydrochloride monohydrate 0.25 mg.</p> <p>Each SIMIPEX 1 mg tablet contains pramipexole dihydrochloride monohydrate 1 mg.</p>
Potential allergens	No allergens

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

What SIMIPEX looks like

SIMIPEX tablets are round and white for each strength.

SIMIPEX 0.125 mg tablets are marked with an "A" on one side of the tablet and are available in blister packs of 30 tablets. (Aust R 172017).

SIMIPEX 0.25 mg tablets are marked with a "B" on one side of the tablet and are available in blister packs of 100 tablets. (Aust R 172018).

SIMIPEX 1 mg tablets are marked with a "D" on one side of the tablet and are available in blister packs of 100 tablets. (Aust R 172021).

SIMIPEX tablets 0.5 (marked with a "C" on one side of the tablet) and 1.5 mg tablets (marked with an "E" on one side of the tablet) are not currently marketed in Australia.

Who distributes SIMIPEX

Arrow Pharma Pty Ltd

15-17 Chapel St

Cremorne VIC 3121

www.arrowpharma.com.au

This leaflet was prepared in December 2022