

SIMIPEX XR modified release tablets

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 SIMIPEX XR?

SIMIPEX XR contains the active ingredient Pramipexole dihydrochloride monohydrate. SIMIPEX XR is used to treat the symptoms of Parkinson's disease. For more information, see Section [1. Why am I taking SIMIPEX XR?](#) in the full CMI.

2. What should I know before I take SIMIPEX XR?

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

3. What if I am taking other medicines?

Some medicines may interfere with SIMIPEX XR 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 SIMIPEX XR?

- 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.
- Swallow the tablet whole with a full glass of water. Do not chew, divide or crush SIMIPEX XR.
- SIMIPEX XR tablets can be taken with or without food. Take SIMIPEX XR at about the same time each day.

More instructions can be found in Section [4. How do I take SIMIPEX XR?](#) in the full CMI.

5. What should I know while taking SIMIPEX XR?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are taking SIMIPEX XR.• Remind any doctor, dentist or pharmacist you visit that you are taking SIMIPEX XR.• Tell your doctor as soon as possible if there is any worsening of your condition or if you feel that SIMIPEX XR is not helping your condition.• Tell your doctor if, you have not used SIMIPEX XR 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	<ul style="list-style-type: none">• Do not chew, divide or crush SIMIPEX XR.• Do not give SIMIPEX XR to anyone else, even if they have the same condition as you• Do not stop taking SIMIPEX XR or change the dose 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	<ul style="list-style-type: none">• SIMIPEX XR may cause drowsiness, hallucinations and episodes of sudden onset of sleep, in some people. If affected, do not drive or operate machinery.
Drinking alcohol	<ul style="list-style-type: none">• Be careful when drinking alcohol while taking SIMIPEX XR. Combining SIMIPEX XR and alcohol can make you more drowsy or sleepy.
Looking after your medicine	<ul style="list-style-type: none">• Keep SIMIPEX XR where children cannot reach it.• Keep SIMIPEX XR in a cool dry and dark place where the temperature is below 25°C.

For more information, see Section [5. What should I know while taking SIMIPEX XR?](#) 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 (dyspnoea), shortness of breath, swelling of the feet or legs due to fluid build-up (heart failure). 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.

SIMIPEX XR modified release tablets

Active ingredient(s): *pramipexole dihydrochloride monohydrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking SIMIPEX XR. **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 SIMIPEX XR.**

Where to find information in this leaflet:

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

1. Why am I taking SIMIPEX XR?

SIMIPEX XR 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. It is believed that SIMIPEX XR works by having a similar effect as dopamine in the brain which may help in conditions where there is not enough dopamine produced in the brain.

SIMIPEX XR 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 binds to dopamine receptors and relays messages in the part of the brain that controls movement. When too little dopamine is produced, this results in Parkinson's disease. SIMIPEX XR works by having a similar effect as dopamine in the brain.

2. What should I know before I take SIMIPEX XR?

Warnings

Do not take SIMIPEX XR 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 use this medicine.

SIMIPEX XR 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.

Ask your doctor if you have any questions about why SIMIPEX XR has been prescribed for you.

SIMIPEX XR is not addictive.

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.
- take any medicines for any other reason
- have allergies to any other medicines or any other substances, such as foods, preservatives or dyes.
- have, or have had, any of the following conditions:
 - kidney problems
 - mental illness
 - low blood pressure
 - trouble controlling your muscles (*dyskinesia*).
- have not told your doctor or pharmacist about any of the above, tell them before you start taking or are given SIMIPEX XR.

It is essential that your doctor knows your medical history before prescribing SIMIPEX XR.

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

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

Your doctor can discuss with you the benefits and risks of taking SIMIPEX XR.

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

SIMIPEX XR is not recommended during breastfeeding, as it may pass into breast milk and there is a possibility that your baby may be affected.

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

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 XR and affect how it works. These include:

- levodopa, levodopa/carbidopa combination, or other medicines used to treat Parkinson's disease (e.g. amantadine)
- medicines used to treat high blood pressure or heart problems (e.g. digoxin, diltiazem, procainamide, quinidine, triamterene, verapamil, hydrochlorothiazide)
- medicines used to treat mental illness/psychoses
- metoclopramide, a medicine used to treat nausea and vomiting
- some medicines used to treat stomach or duodenal ulcers (e.g. cimetidine or ranitidine)
- quinine, a medicine used to prevent malaria
- some antibiotics (e.g. trimethoprim, cephalosporins, penicillins)
- indomethacin, 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 XR 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 will advise you. Your doctor and pharmacist may have more information on medicines to be careful with or to avoid while taking SIMIPEX XR.

4. How do I take SIMIPEX XR?

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

They may differ from the information contained in this leaflet.

SIMIPEX XR is available in a number of tablet strengths. Your doctor or pharmacist will tell you which strength of SIMIPEX XR tablet and 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 label, 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 the instructions provided and use SIMIPEX XR until your doctor tells you to stop.

If you are switching from the immediate-release pramipexole tablets:

Your doctor will base your dose of SIMIPEX XR tablets on the dose of the immediate-release Pramipexole tablets you were taking.

Take your immediate-release Pramipexole tablets as normal the day before you switch. Then take your modified release SIMIPEX XR tablets the next morning and do not take any more of the immediate-release Pramipexole tablets.

When to take SIMIPEX XR

- **Take SIMIPEX XR 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 XR

- **Swallow the tablet whole with a full glass of water.**
- **Do not chew, divide, or crush SIMIPEX XR**
- SIMIPEX XR tablets can be taken with or without food.

If you forget to take SIMIPEX XR

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 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 use your medicine, ask your pharmacist for some hints.

If you take too much SIMIPEX XR

If you think that you have taken too much SIMIPEX XR, 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.

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

5. What should I know while taking SIMIPEX XR?

Things you should do

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

Be careful getting up from a sitting or lying position. You may feel dizzy or lightheaded while taking SIMIPEX XR,

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.**

If you feel that SIMIPEX XR is not helping your condition, tell your doctor or pharmacist

Tell your doctor if, for any reason, you have not used SIMIPEX XR 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 SIMIPEX XR than what your doctor has prescribed. This is called Dopamine Dysregulation Syndrome (DDS) and can lead you to taking too much SIMIPEX XR. This could increase your risk of experiencing side effects. If you feel the desire to take more SIMIPEX XR 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 notice parts of SIMIPEX XR tablets in your stool (faeces). This may look like whole tablets.

Your doctor may need to assess your response to therapy.

Tell your doctor if you experience symptoms such as depression, apathy, anxiety, fatigue, sweating or pain after stopping or reducing your SIMIPEX XR 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.

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

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

Things you should not do

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

Do not stop taking SIMIPEX XR or change the dose without checking with your doctor.

It is important not to suddenly stop taking your SIMIPEX XR 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 XR, the dose will normally need to be reduced gradually over several days.

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 SIMIPEX XR 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 SIMIPEX XR affects you.

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

Make sure you know how you react to SIMIPEX XR 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 SIMIPEX XR. Combining SIMIPEX XR and alcohol can make you more drowsy or sleepy.

Looking after your medicine

- Keep SIMIPEX XR in the pack until it is time to take it.
- Keep SIMIPEX XR in a cool dry place where the temperature stays below 30°C.

Follow the instructions in the carton on how to take care of your medicine properly.

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 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 about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • feeling sick (nausea) • vomiting • constipation • diarrhoea • dry mouth • drowsiness • tiredness • 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 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 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

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

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • 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 • confusion or hallucinations (seeing, feeling or hearing things that are not there) • mental illness causing severe suspiciousness (<i>paranoia</i>) • shortness of breath or tightness in the chest (<i>dyspnoea</i>) • shortness of breath, swelling of the feet or legs due to fluid build-up (<i>heart failure</i>) 	<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>

These are serious side effects. You may need urgent medical attention or hospitalization. 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 SIMIPEX XR contains

Active ingredient (main ingredient)	pramipexole dihydrochloride monohydrate
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • calcium hydrogen phosphate • hypromellose • magnesium stearate • silicon dioxide <p>Each SIMIPEX XR 0.375 mg modified release tablet contains 0.375 mg pramipexole dihydrochloride monohydrate.</p> <p>Each SIMIPEX XR 0.75 mg modified release tablet contains 0.75 mg pramipexole dihydrochloride monohydrate.</p> <p>Each SIMIPEX XR 1.5 mg modified release tablet contains 1.5 mg pramipexole dihydrochloride monohydrate.</p> <p>Each SIMIPEX XR 2.25 mg modified release tablet contains 2.25 mg pramipexole dihydrochloride monohydrate.</p> <p>Each SIMIPEX XR 3 mg modified release tablet contains 3 mg pramipexole hydrochloride monohydrate.</p> <p>Each SIMIPEX XR 3.75 mg modified release tablet contains 3.75 mg pramipexole dihydrochloride monohydrate.</p> <p>Each SIMIPEX XR 4.5 mg modified release tablet contains 4.5 mg pramipexole dihydrochloride monohydrate.</p>
Potential allergens	-

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

What SIMIPEX XR looks like

SIMIPEX XR 0.375mg modified release tablets are white or nearly white, cylindrical, plans and bevel tablets marked with 026 on one side. (Aust R 225592)

SIMIPEX XR 0.75mg modified release tablets are white or nearly white, cylindrical and biconvex tablets marked with 052 on one side. (Aust R 225573)

SIMIPEX XR 1.5mg modified release tablets are white or nearly white, cylindrical and biconvex tablets marked with 105 on one side. (Aust R 225603)

SIMIPEX XR 2.25mg modified release tablets are white or nearly white, cylindrical and biconvex tablets marked with 157 on one side. (Aust R 225626)

SIMIPEX XR 3mg modified release tablets are white or nearly white, cylindrical and biconvex tablets marked with 210 on one side. (Aust R 225605)

SIMIPEX XR 3.75mg modified release tablets are white or nearly white, cylindrical and biconvex tablets marked with 262 on one side. (Aust R 225578)

SIMIPEX XR 4.5mg modified release tablets are white or nearly white, cylindrical, plans and bevel tablets marked with 315 on one side. (Aust R 225628)

SIMIPEX XR modified release tablets are available in seven strengths: 0.375mg, 0.75mg, 1.5mg, 2.25mg, 3mg, 3.75mg and 4.5mg.

SIMIPEX XR are available in blister packs of 10 and 30 modified release tablets.

*Not all strengths and pack sizes of SIMIPEX XR modified release tablets are being distributed in Australia.

Who distributes SIMIPEX XR

Arrotex Pharmaceuticals Pty Ltd
15 – 17 Chapel Street
Cremorne VIC 3121
Australia
www.arrotex.com.au

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