

SIMPEX XR modified release tablets

Pramipexole dihydrochloride monohydrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about SIMPEX XR.

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 SIMPEX XR against the benefits it is expected to have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What SIMPEX XR is used for

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

How SIMPEX XR works

SIMPEX 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.

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

Your doctor may have prescribed SIMPEX XR for another reason.

SIMPEX XR is not addictive.

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

Use in children

SIMPEX 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.

Before you take SIMPEX XR

When you must not take it

Do not take SIMPEX XR if you are allergic to:

- pramipexole dihydrochloride monohydrate or
- any of the other ingredients in SIMPEX XR listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath

- wheezing or difficulty breathing
- rash, itching or hives on the skin
- swelling of the face, lips, tongue or other parts of the body.

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 SIMPEX 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.

If you are not sure whether you should start taking SIMPEX XR, 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 benefits and risks of taking SIMPEX XR.

Tell your doctor if you are breastfeeding, or likely to

breastfeed during your course of medication.

SIMPEX 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 SIMPEX XR.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and SIMPEX XR 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 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 SIMPEX 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 SIMPEX XR.

How to take SIMPEX XR

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

They may differ from the information contained in this leaflet.

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

Your doctor will base your dose of SIMPEX 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 SIMPEX XR tablets the next morning and do not take any more of the

immediate-release Pramipexole tablets.

How to take it

Swallow the tablet whole with a full glass of water.

Do not chew, divide or crush SIMPEX XR.

SIMPEX XR tablets can be taken with or without food.

When to take it

Take SIMPEX 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 long to take it

Continue taking SIMPEX XR 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 take it

If it is almost time for your next dose, skip the dose you missed and take the 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 that you have 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 (overdose)

Immediately telephone your doctor, pharmacist or Poisons Information Centre (telephone 13

11 26) for advice, or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much SIMIPEX XR. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much SIMIPEX XR you may have nausea, vomiting, abnormal uncontrolled movements, hallucinations, agitation and dizziness or light-headedness.

While you are taking SIMIPEX XR

Things you must do

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

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.

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 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.

Things you must 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.

If your doctor asks you to stop taking SIMIPEX XR, 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 SIMIPEX XR 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 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.

Be careful when drinking alcohol while taking SIMIPEX XR.

Combining SIMIPEX XR 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 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.

Side effects

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

SIMIPEX XR 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 these lists of possible side effects.

You may not experience any of them.

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

Tell your doctor 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*)
- 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.

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 hospitalization. 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 using SIMIPEX XR

Storage

Keep SIMIPEX XR in the pack until it is time to take it.

If you take the tablets out of the pack they may not keep well.

Keep SIMIPEX XR in a cool dry place where the temperature stays below 25°C.

Do not store SIMIPEX XR or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills. Heat and dampness can destroy some medicines.

Keep your SIMIPEX XR where young 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

SIMIPEX XR is the brand name of your medicine.

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

- SIMIPEX XR 0.375 mg modified release tablets are white or nearly white, cylindrical, plans and bevel tablets marked with 026 on one side.
- SIMIPEX XR 0.75 mg modified release tablets are white or nearly white, cylindrical and biconvex tablets marked with 052 on one side.

- SIMIPEX XR 1.5 mg modified release tablets are white or nearly white, cylindrical and biconvex tablets marked with 105 on one side.
- SIMIPEX XR 2.25mg modified release tablets are white or nearly white, cylindrical and biconvex tablets marked with 157 on one side.
- SIMIPEX XR 3 mg modified release tablets are white or nearly white, cylindrical and biconvex tablets marked with 210 on one side.
- SIMIPEX XR 3.75mg modified release tablets are white or nearly white, cylindrical and biconvex tablets marked with 262 on one side.
- SIMIPEX XR 4.5 mg modified release tablets are white or nearly white, cylindrical, plans and bevel tablets marked with 315 on one side.

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

Not all pack sizes may be available.

Ingredients

- Each SIMIPEX XR 0.375 mg modified release tablet contains 0.375 mg pramipexole dihydrochloride monohydrate.
- Each SIMIPEX XR 0.75 mg modified release tablet contains 0.75 mg pramipexole dihydrochloride monohydrate.
- Each SIMIPEX XR 1.5 mg modified release tablet contains 1.5 mg pramipexole dihydrochloride monohydrate.
- Each SIMIPEX XR 2.25 mg modified release tablet contains 2.25 mg pramipexole dihydrochloride monohydrate.
- Each SIMIPEX XR 3 mg modified release tablet contains 3 mg pramipexole dihydrochloride monohydrate.
- Each SIMIPEX XR 3.75 mg modified release tablet contains

3.75 mg pramipexole
dihydrochloride monohydrate.

- Each SIMIPEX XR 4.5 mg modified release tablet contains 4.5 mg pramipexole dihydrochloride monohydrate.

Each SIMIPEX XR tablet also contains the following ingredients:

- hypromellose
- calcium hydrogen phosphate anhydrous
- silicon dioxide
- magnesium stearate.

Distributor

Arrow Pharma Pty Ltd
15 - 17 Chapel Street
Cremorne Victoria 3121

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Australian Registration Numbers:

- SIMIPEX XR 0.375 mg modified release tablets AUST R 225592
- SIMIPEX XR 0.75 mg modified release tablets AUST R 225573
- SIMIPEX XR 1.5 mg modified release tablets AUST R 225603
- SIMIPEX XR 2.25mg modified release tablets AUST R 225626
- SIMIPEX XR 3 mg modified release tablets AUST R 225605
- SIMIPEX XR 3.75 mg modified release tablets AUST R 225578
- SIMIPEX XR 4.5 mg modified release tablets AUST R 225628