

Simipex

Pramipexole dihydrochloride monohydrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about SIMIPEX. It does not contain all the information and does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risk of you taking SIMIPEX against the benefits they expect it will have for you.

Talk to your doctor or pharmacist if you have any concerns about taking this medicine.

Keep this leaflet with the medicine.

You may need to read it again.

What SIMIPEX is used for

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

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

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

Your doctor may have prescribed SIMIPEX for another reason.

SIMIPEX is not addictive.

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

Before you take SIMIPEX

When you must not take it

Only use SIMIPEX if it has been prescribed for you by a doctor. Never give it to someone else even if their symptoms seem to be the same as yours.

Do not take SIMIPEX if you are allergic to pramipexole or any of the other ingredients listed at the end of this leaflet.

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

Signs of an allergic reaction may include

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

You should not use SIMIPEX after the EXPIRY DATE on the carton or blister strips, or if the packaging is torn or damaged.

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, 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.

Before using SIMIPEX, it is important to tell your doctor if you are taking any other medicines, obtained with or without a doctor's prescription.

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

Some medicines and SIMIPEX may interfere with each other. These include:

- any medicines for the treatment of Restless Legs Syndrome
- 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 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 will advise you.

Ask for your doctor's advice if you are pregnant, or likely to become pregnant during your course of medication.

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.

Ask for your doctor's advice if you are breastfeeding, or likely 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 children below 18 years of age.

How to take SIMIPEX

How to take it

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.

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

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.

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

When to take it

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 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 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 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.

If you are not sure what to do, check with your doctor or pharmacist.

If you have taken too much SIMIPEX (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.

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.

While you are taking SIMIPEX

Things you must do

Tell all doctors and pharmacists who are treating you 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 must not do

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

Things to be careful of

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.

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.

Side effects

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 these lists 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 for the advice of your doctor or pharmacist if you have any concerns about the effects of taking SIMIPEX.

The most common side effects of SIMIPEX include:

- 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.

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.

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

- 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 buildup (heart failure)

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

Tell your doctor as soon as you notice anything else that is making you unwell. Other side effects not yet known or listed above, may also occur in some patients.

After taking SIMIPEX

Storage

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

SIMIPEX should be kept in a cool dry and dark place where the temperature stays 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.

Keep your medicine 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

Return any unused medicine to your pharmacist so that it can be disposed of safely.

Product Description

SIMIPEX is the brand name of your medicine.

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.

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.

SIMIPEX 1 mg tablets are marked with a “D” on one side of the tablet and are available in blister packs of 100 tablets.

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.

The following Australian Registration Numbers appear on the carton:

SIMIPEX 0.125 mg tablets: AUST R 172017

SIMIPEX 0.25 mg tablets: AUST R 172018

SIMIPEX 1 mg tablets: AUST R 172021

Ingredients

Each SIMIPEX 0.125 mg tablet contains pramipexole dihydrochloride monohydrate 0.125 mg.

Each SIMIPEX 0.25 mg tablet contains pramipexole dihydrochloride monohydrate 0.25 mg.

Each SIMIPEX 1 mg tablet contains pramipexole dihydrochloride monohydrate 1 mg.

The other ingredients found in all strengths are:

- mannitol
- pregelatinised maize starch
- microcrystalline cellulose
- povidone
- purified talc
- magnesium stearate

Supplier

Arrow Pharma Pty Ltd
15 – 17 Chapel Street
Cremorne, Victoria, 3121.

This leaflet was prepared in December 2020.