

Sifrol®

Tablets

pramipexole dihydrochloride monohydrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Sifrol.

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 Sifrol against the benefits it is expected to have for you.

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

This leaflet was last updated on the date at the end of this leaflet. More recent information may be available. The latest Consumer Medicine Information is available from your pharmacist, doctor, or from www.medicines.org.au and may contain important information about the medicine and its use of which you should be aware.

Keep this leaflet with your medicine.

You may need to read it again.

What Sifrol is used for

Sifrol is used to treat the symptoms of Parkinson's disease and Restless Legs Syndrome (RLS).

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.

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 sensations 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 asleep. 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.

How Sifrol works

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

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

Your doctor may have prescribed it for another reason.

Sifrol is not addictive.

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

Before you take Sifrol

When you must not take it

Do not take Sifrol if you have an allergy to:

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

Some of the symptoms 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.

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, or any other substances, such as 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 plan to become pregnant.

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

Tell your doctor if you are breastfeeding, or plan to breastfeed.

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

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

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 Sifrol 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)
- indometacin, a medicine used to treat arthritis
- chlorthalidamide, 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 Sifrol 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 Sifrol.

How to take Sifrol

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

They may differ from the information contained in this leaflet.

Sifrol is available in a number of tablet strengths. Your doctor or pharmacist will tell you which strength of Sifrol 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 dose varies from patient to patient. Your doctor may first start you on a low dose of Sifrol and slowly increase the amount of Sifrol until the right dose is reached to control your condition.

PARKINSON'S DISEASE

The usual starting dose is one Sifrol 0.125 mg tablet three times a day.

Depending on how you respond to the treatment, your doctor may increase your daily dose gradually in steps of 0.75 mg at weekly intervals until the right dose for your needs is reached. The maximum dose is 4.5 mg of Sifrol per day.

RESTLESS LEGS SYNDROME

The usual starting dose is one Sifrol 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 Sifrol per day.

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

How to take it

Swallow the tablets with a full glass of water.

Sifrol can be taken with or without food.

When to take it

Take Sifrol 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 Sifrol 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

PARKINSON'S DISEASE

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.

RESTLESS LEGS SYNDROME

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

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

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

You may need urgent medical attention.

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

While you are taking Sifrol

Things you must do

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

Tell your doctor or pharmacist if you feel that Sifrol is not helping your condition.

Some people taking long-term Sifrol treatment for Restless Legs Syndrome may experience more intense, spreading, or worsening symptoms.

Tell your doctor if, for any reason, you have not used Sifrol 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 Sifrol 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 Sifrol to anyone else, even if they have the same condition as you.

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

It is important not to suddenly stop taking your Sifrol tablets, unless advised to do so by your doctor. If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects.

If you are using Sifrol for your Parkinson's Disease and your doctor asks you to stop taking Sifrol, the dose will normally be reduced gradually over several days.

Things to be careful of

Be careful driving or operating machinery until you know how Sifrol 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 Sifrol 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 Sifrol.

Combining Sifrol 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 Sifrol, especially during the first few weeks of treatment. If you wish to stand up, you should do so slowly.

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

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

Side effects

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

Sifrol helps most people with Parkinson's disease or RLS, 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
- uncontrollable twitching, jerking or writhing movements
- 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
- 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 Sifrol

Storage

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

Keep Sifrol in a cool dry place where the temperature stays below 30°C.

Do not store Sifrol 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 Sifrol 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

Sifrol is the brand name of your medicine.

Sifrol 0.125 mg tablets are round, white tablets with 'P6' on one side and company symbol on the other.

Sifrol 0.25 mg tablets are oval, white, scored tablets with 'P7' on one side and company symbol on the other.

Sifrol 1 mg tablets are round, white, scored tablets with 'P9' on one side and company symbol on the other.

Sifrol 0.25 mg and 1 mg tablets are available in blister packs of 10 (sample pack)* and 100 tablets.

Sifrol 0.125 mg tablets are available in blister packs of 10 (sample pack)*, 30 and 100* tablets.

* Not distributed in Australia.

Ingredients

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

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

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

Each Sifrol tablet also contains the following ingredients:

- mannitol
- maize starch
- colloidal anhydrous silica
- povidone
- magnesium stearate.

Supplier

Sifrol tablets are supplied in Australia by:

Boehringer Ingelheim Pty Limited

ABN 52 000 452 308

Sydney, Australia

www.boehringer-ingelheim.com.au

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Australian Registration Numbers

Sifrol 0.125 mg tablets

AUST R 67238

Sifrol 0.25 mg tablets

AUST R 66484

Sifrol 1 mg tablets

AUST R 66485