

# Sifrol®

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## **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.

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### **1. Why am I taking Sifrol?**

Sifrol contains the active ingredient pramipexole dihydrochloride monohydrate. Sifrol is used to treat the symptoms of Parkinson's disease and Restless Legs Syndrome.

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

### **2. What should I know before I take Sifrol?**

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

### 3. What if I am taking other medicines?

Some medicines may interfere with Sifrol 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 Sifrol?

The dose you should take and how often you take it, will depend on the condition that you are being treated for.

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

### 5. What should I know while taking Sifrol?

Things you should do	
	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are taking Sifrol</li><li>• Tell your doctor as soon as possible if there is any worsening of your condition or if you feel</li></ul>

	<p>that Sifrol is not helping your condition</p> <ul style="list-style-type: none"> <li>• Tell your doctor if, you have not used Sifrol exactly as prescribed</li> <li>• Be careful getting up from a sitting or lying position</li> <li>• Monitor your skin and see your doctor in case of any concerns</li> </ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>• Do not give Sifrol to anyone else, even if they have the same condition as you</li> <li>• Do not stop taking Sifrol or change the dose without checking with your doctor</li> <li>• Do not give this medicine to a child or adolescent under the age of 18 years.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• Be careful driving or operating machinery as Sifrol can cause drowsiness and hallucinations.</li> </ul>

<b>Drinking alcohol</b>	<ul style="list-style-type: none"> <li>Combining Sifrol and alcohol can make you more drowsy or sleepy.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>Keep Sifrol in a cool dry place, below 30°C. Keep it stored in the pack.</li> </ul>

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

## 6. Are there any side effects?

Tell your doctor immediately if you or your family notice any of the following side effects: memory loss, fainting, signs of allergy such as skin rash; swelling of the face, lips, tongue or other body parts; difficulty breathing; excessive sleepiness; compulsive behaviour such as gambling, hypersexuality, shopping, medication use and repetitive, purposeless activities; severe suspiciousness; shortness of breath or tightness in the chest; swelling of the feet or legs.

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.

# Sifrol®

**Active ingredient:** *pramipexole dihydrochloride monohydrate*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about taking Sifrol. **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 Sifrol.**

**Where to find information in this leaflet:**

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

## 1. Why am I taking Sifrol?

**Sifrol contains the active ingredient pramipexole dihydrochloride monohydrate.**

**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 in the brain. 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 which may help in conditions where there is not enough dopamine produced or dopamine signalling 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.

## **2. What should I know before I take Sifrol?**

### **Warnings**

#### **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.

#### **Check with your doctor if you:**

- take any medicines for any other condition
- are not sure whether you should start taking this medicine

- have allergies to any other medicines, or any other substances, such as foods, preservatives or dyes
- have, or have had, any of the following medical conditions:
  - kidney problems
  - mental illnesses
  - low blood pressure
  - trouble controlling your muscles (dyskinesia).
- have not told your doctor or pharmacist about any of the above. Do so before you start taking Sifrol.

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

Talk to your doctor if you are breastfeeding or intend to breastfeed. Sifrol ER is not recommended during breastfeeding, as it may pass into breast milk and there is a possibility that your baby may be affected.

### **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 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
- 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 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.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Sifrol.**

## **4. How do I 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.

If you have stopped taking your medicine for more than a few days, speak with your doctor before you restart your medication.

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

## **When to take Sifrol**

**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 to take Sifrol**

**Swallow the tablets with a full glass of water.**

Sifrol can be taken with or without food.

**Continue taking Sifrol for as long as your doctor tells you.**

Sifrol 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 Sifrol**

### **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 Sifrol**

**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.**

**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.**

## **5. What should I know while taking Sifrol?**

### **Things you should do**

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

**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.

**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 taken Sifrol 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 SIFROL than what your doctor has prescribed. This is called Dopamine Dysregulation Syndrome (DDS) and can lead you to

taking too much SIFROL. This could increase your risk of experiencing side effects. If you feel the desire to take more SIFROL 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 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.**

**Call your doctor straight away if:**

- there is any worsening of your condition.

Some people taking Sifrol for treatment of Restless Legs Syndrome may experience earlier onset of symptoms (in the evening or even in the afternoon), increase in symptoms and spreading of symptoms to other limbs.

**Things you should 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 taking 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.

**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.

## **Driving or using machines**

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

Sifrol 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.**

## **Drinking alcohol**

**Be careful when drinking alcohol while taking Sifrol.**

Combining Sifrol and alcohol can make you more drowsy or sleepy.

## **Looking after your medicine**

**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.

## **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**

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"><li>• feeling sick (nausea)</li><li>• vomiting</li><li>• constipation</li><li>• diarrhoea</li><li>• dry mouth</li><li>• drowsiness</li><li>• tiredness</li><li>• restlessness</li><li>• dizziness</li><li>• headache</li><li>• light-headedness on standing up, especially when getting up from a sitting or lying position (hypotension)</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>• blurred vision</li> <li>• swelling of hands, ankles or feet</li> <li>• uncontrollable twitching, jerking or writhing movements</li> <li>• difficulty sleeping or unusual dreams</li> <li>• weight gain or loss</li> <li>• loss or gain of sexual drive</li> <li>• forward bending of the head and neck.</li> </ul>	

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

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<p><b>[Grouping 1 as per effect on body e.g. bleeding-related]:</b></p> <ul style="list-style-type: none"> <li>• loss of memory (amnesia)</li> <li>• fainting</li> </ul>	<p><b>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.</b></p>

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• 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</li> <li>• excessive sleepiness or sudden onset of sleep during normal daily activities</li> <li>• compulsive behaviour such as gambling, hypersexuality, shopping, eating, medication use and repetitive purposeless activities</li> <li>• confusion or hallucinations (seeing, feeling or hearing things that are not there)</li> <li>• mental illness causing severe suspiciousness (paranoia)</li> <li>• shortness of breath or tightness in the chest</li> </ul>	

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

**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](http://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 Sifrol contains

<b>Active ingredient (main ingredient)</b>	pramipexole dihydrochloride monohydrate
<b>Other ingredients (inactive ingredients)</b>	mannitol maize starch colloidal anhydrous silica povidone magnesium stearate.

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

## What Sifrol looks like

Sifrol 0.125 mg tablets (AUST R 67238) are round, white tablets with 'P6' on one side and company symbol on the other.

Sifrol 0.25 mg tablets (AUST R 66484) are oval, white, scored tablets with 'P7' on one side and company symbol on the other.

Sifrol 1 mg tablets (AUST R 66485) are round, white, scored tablets with 'P9' on one side and company symbol on the other.

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

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

\* Not distributed in Australia.

## **Who distributes Sifrol**

Sifrol tablets are supplied in Australia by:

Boehringer Ingelheim Pty Limited

ABN 52 000 452 308

Sydney, Australia

[www.boehringer-ingelheim.com.au](http://www.boehringer-ingelheim.com.au)

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