

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 Sifrol ER?

Sifrol ER contains the active ingredient pramipexole dihydrochloride monohydrate. Sifrol ER is used to treat the symptoms of Parkinson's disease.

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

2. What should I know before I take Sifrol ER?

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

3. What if I am taking other medicines?

Some medicines may interfere with Sifrol ER 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 ER?

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 ER?](#) in the full CMI.

5. What should I know while taking Sifrol ER?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are taking Sifrol ER • Tell your doctor as soon as possible if there is any worsening of your condition or if you feel that Sifrol ER is not helping your condition • Tell your doctor if, you have not taken Sifrol ER 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	• Do not give Sifrol ER to anyone else, even if they have the same condition as you • Do not stop taking Sifrol ER 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	• Be careful driving or operating machinery as Sifrol ER can cause drowsiness and hallucinations.
Drinking alcohol	• Combining Sifrol ER and alcohol can make you more drowsy or sleepy.
Looking after your medicine	• Keep Sifrol ER in a cool dry place, below 30°C. Keep it stored in the pack.

For more information, see Section [5. What should I know while taking Sifrol ER?](#) 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® ER

Active ingredient: *pramipexole dihydrochloride monohydrate*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I taking Sifrol ER?

Sifrol ER contains the active ingredient pramipexole dihydrochloride monohydrate.

Sifrol ER 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 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.

How Sifrol ER works

Sifrol ER 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 ER 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.

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

Your doctor may have prescribed it for another reason.

Sifrol ER is not addictive.

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

2. What should I know before I take Sifrol ER?

Warnings

Do not take Sifrol ER 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 ER.

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 ER 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 ER 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 ER.

4. How do I take Sifrol ER?

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

They may differ from the information contained in this leaflet.

Sifrol ER is available in a number of tablet strengths. Your doctor or pharmacist will tell you which strength of Sifrol ER 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.

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

Your doctor will base your dose of Sifrol ER tablets on the dose of the immediate-release Sifrol tablets you were taking.

Take your immediate-release Sifrol tablets as normal the day before you switch. Then take your extended-release Sifrol ER tablets the next morning and do not take any more of the immediate-release Sifrol tablets.

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

When to take Sifrol ER

Take Sifrol ER 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 ER

Swallow the tablet whole with a full glass of water.

Do not chew, divide or crush Sifrol ER.

Sifrol ER tablets can be taken with or without food.

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

Sifrol ER 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 ER

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 take your medicine, ask your pharmacist for some hints.

If you take too much Sifrol ER

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 ER you may have nausea, vomiting, abnormal uncontrolled movements, hallucinations, agitation and dizziness or light-headedness.

5. What should I know while taking Sifrol ER?

Things you should do

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

Be careful getting up from a sitting or lying position.

You may feel dizzy or lightheaded while taking Sifrol ER, 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 ER is not helping your condition.

Tell your doctor if, for any reason, you have not taken Sifrol ER 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 notice parts of Sifrol ER 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 Sifrol ER 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.

Things you should not do

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

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

It is important not to suddenly stop taking your Sifrol ER 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 ER for your Parkinson's Disease and your doctor asks you to stop taking Sifrol ER, 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 ER affects you.

Sifrol ER may cause drowsiness, hallucinations and episodes of sudden onset of sleep in some people.

Make sure you know how you react to Sifrol ER 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 ER.

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

Looking after your medicine

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

Do not store Sifrol ER 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 ER 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

Less serious side effects	What to do
• 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	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
• 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.

Serious side effects

Serious side effects	What to do
[Grouping 1 as per effect on body e.g. bleeding-related]: • 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 (paranoia) • shortness of breath or tightness in the chest • swelling of the feet or legs due to fluid build-up (heart failure).	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.

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 Sifrol ER contains

Active ingredient (main ingredient)	pramipexole dihydrochloride monohydrate
Other ingredients (inactive ingredients)	hypromellose maize starch carbomer 941 colloidal anhydrous silica magnesium stearate

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

What Sifrol ER looks like

Sifrol ER is the brand name of your medicine.

Sifrol ER 0.375 mg extended-release tablets (AUST R 158754) are white to off-white, round, biconvex, bevel-edged tablets, with 'P1' on one side and BI company symbol on the other.

Sifrol ER 0.75 mg extended-release tablets (AUST R 158755) are white to off-white, round, biconvex, bevel-edged tablets, with 'P2' on one side and BI company symbol on the other.

Sifrol ER 1.5 mg extended-release tablets (AUST R 158757) are white to off-white, oval, biconvex, tablets, with 'P3' on one side and BI company symbol on the other.

Sifrol ER 2.25 mg extended-release tablets (AUST R 173901) are white to off-white, oval, biconvex tablets with 'P12' on one side and BI company symbol on the other.

Sifrol ER 3 mg extended-release tablets (AUST R 158763) are white to off-white, oval, biconvex, tablets, with 'P4' on one side and BI company symbol on the other.

Sifrol ER 3.75 mg extended-release tablets (AUST R 173921) are white to off-white, oval, biconvex tablets with 'P13' on one face and BI company symbol on the other.

Sifrol ER 4.5 mg extended-release tablets (AUST R 158764) are white to off-white, oval, biconvex, tablets, with 'P5' on one side and BI company symbol on the other.

Sifrol ER is available in blister packs of 30 extended-release tablets. Sifrol ER 0.375 mg and 0.75 mg are also available in blister packs of 10 (sample pack)* extended-release tablets.

* Not distributed in Australia.

Who distributes Sifrol ER

Sifrol ER tablets are supplied in Australia by:

Boehringer Ingelheim Pty Limited

ABN 52 000 452 308

Sydney, Australia

www.boehringer-ingelheim.com.au

This leaflet was prepared in September 2025.

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