

# **Sifrol® ER**

## **extended-release tablets**

Pramipexole hydrochloride

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### **Consumer Medicine Information**

#### **What is in this leaflet**

This leaflet answers some common questions about Sifrol ER. It does not contain all available information, nor does it take the place of talking to 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](http://www.medicines.org.au) and may contain important information about the medicine and its use of which you should be aware.

#### **Keep this information with your Sifrol ER.**

You may need to read it again later.

**You should ask your doctor or pharmacist if you have any questions about Sifrol ER or if you have any trouble before, during or after using Sifrol ER.**

## **What Sifrol ER is used for**

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

Sifrol ER contains the active ingredient Pramipexole hydrochloride. Pramipexole hydrochloride belongs to a group of medicines known as "dopamine agonists".

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

Your doctor may have prescribed Sifrol ER for another reason.

## **Before you take Sifrol ER**

### **When you must not take Sifrol ER**

**Only use Sifrol ER 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 Sifrol ER if you are allergic to pramipexole or any of the other ingredients in Sifrol ER.**

The ingredients in SIFROL ER are 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.**

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 troubled breathing

**Do not take Sifrol ER after the EXPIRY DATE printed on the carton or blister strips.**

If you take it after the expiry date has passed, it may not work as well.

**Do not take Sifrol ER if the packaging is torn or shows signs of tampering.**

## **Before you start to take Sifrol ER**

**It is essential that your doctor knows your medical history before prescribing Sifrol ER.**

**Before taking Sifrol ER, you must tell your doctor if you have, or have had, any of the following conditions:**

- kidney problems
- mental illnesses
- heart problems
- blood pressure problems
- eye problems

**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 Sifrol ER, 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:**

- any other medicines for the treatment of Restless Legs Syndrome
- levodopa, 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)
- certain medicines used in the treatment of mental illness / psychosis (antipsychotics or neuroleptics)

- metoclopramide - commonly used to help control nausea and vomiting
- cimetidine or ranitidine - used to treat stomach ulcer or reflux
- quinine - used to treat malaria
- trimethoprim - an antibiotic
- medicines used to produce calmness or help you sleep e.g. sleeping tablets, sedatives or tranquillisers, and pain relievers

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.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking Sifrol ER.

## **Pregnancy**

**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 Sifrol ER must be assessed against the possible effects on your unborn child.

## **Breastfeeding**

**Sifrol ER 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, Sifrol ER was shown to pass into breast milk, and can stop the production of milk.

## **Children**

The use of Sifrol ER is not recommended in children below 18 years of age.

## **Taking Sifrol ER**

### **How to take Sifrol ER**

**It is important you take Sifrol ER as directed by your doctor.**

A number of tablet strengths of Sifrol ER are available (see Product Description).

**Make sure that you only take the tablet strength that your doctor has prescribed.**

Sifrol ER are extended-release tablets and should be taken once daily, at about the same time each day

**The tablets should be swallowed whole with a glass of water. Do not chew, divide or crush Sifrol ER.**

Sifrol ER tablets can be taken with or without food.

The recommended starting dose for treating Parkinson's disease in adults is one Sifrol ER 0.375 mg tablet once daily, at about the same time each 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 Sifrol ER is 4.5 mg pramipexole hydrochloride.

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

### **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.**

**Ask your doctor for more information if you have been given a different instruction to that referred to above.**

### **If you forget to take a dose**

**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.**

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

## **If you have taken too much Sifrol ER (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 Sifrol ER.**

**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 Sifrol ER**

### **Things you must do**

**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, since your condition may worsen.

If your doctor asks you to stop taking Sifrol ER, 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.**

**If you or your family notices an increase in compulsive behaviour, seek immediate medical advice.**

## **Things to be careful of**

**Do not drive a car, operate machinery, or do anything else that could be dangerous (after taking Sifrol ER) 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.**

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

Combining Sifrol ER 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 ER, 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**

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 Sifrol ER against the expected benefits.

**Ask for the advice of your doctor or pharmacist if you have any concerns about the effects of taking Sifrol ER.**

The most common side effects include:

- nausea
- constipation

- drowsiness
- hallucinations
- confusion
- dizziness
- swelling of hands, ankles or feet (peripheral oedema)
- uncontrolled movements (especially in patients also taking other medicines to treat Parkinson's disease)

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 or without prior warning signs, such as excessive drowsiness.

Other reported side effects include:

- hypersensitivity
- diarrhea
- dry mouth
- fatigue
- visual disturbance including blurred vision and reduced visual acuity
- vomiting

- headache
- lightheadedness or low blood pressure (hypotension)
- trouble sleeping (insomnia)
- amnesia
- restlessness
- dream abnormalities
- delusion
- paranoia
- weight gain
- weight decrease

Compulsive behaviour such as gambling, hypersexuality, shopping, eating, medication use and repetitive purposeless activities have been reported in patients taking dopamine agonists for the treatment of Parkinson's disease, especially at high doses.

**If you or your family notice an increase in compulsive behaviour, seek immediate medical advice.**

Your doctor may consider reducing or ceasing your treatment.

**Tell your doctor as soon as possible if you experience any side effects during or after taking Sifrol ER, so that these effects may be properly treated.**

Other side effects not yet known or listed above, may also occur in some patients.

**You should tell your doctor or pharmacist if you notice anything unusual, during or after taking Sifrol ER.**

## **After taking Sifrol ER**

### **Storage**

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

**Do not store your Sifrol ER in direct sunlight or heat.**

For example, do not leave your Sifrol ER in the car on hot days.

**Keep your Sifrol ER where children cannot reach it.**

### **Disposal**

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

## **Product Description**

### **What is Sifrol ER**

Sifrol ER is the brand name of your medicine.

Sifrol ER are extended-release tablets, and are available in five strengths: 0.375 mg, 0.75 mg, 1.5 mg, 3 mg and 4.5 mg.

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

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

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

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

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

Sifrol ER are available in blister packs of 30 extended-release tablets, except for Sifrol ER 0.375 mg and 0.75 mg which are also available in blister packs of 10 extended-release tablets.

The following Australian Registration Numbers appear on the carton:

Sifrol ER 0.375 mg extended-release tablets AUST R 158754

Sifrol ER 0.75 mg extended-release tablets - AUST R 158755

Sifrol ER 1.5 mg extended-release tablets - AUST R 158757

Sifrol ER 3 mg extended-release tablets - AUST R 158763

Sifrol ER 4.5 mg extended-release tablets - AUST R 158764

## **Ingredients**

Each Sifrol ER 0.375 mg extended-release tablet contains 0.375 mg pramipexole hydrochloride.

Each Sifrol ER 0.75 mg extended-release tablet contains 0.75 mg pramipexole hydrochloride.

Each Sifrol ER 1.5 mg extended-release tablet contains 1.5 mg pramipexole hydrochloride.

Each Sifrol ER 3 mg extended-release tablet contains 3 mg pramipexole hydrochloride.

Each Sifrol ER 4.5 mg extended-release tablet contains 4.5 mg pramipexole hydrochloride.

The other ingredients found in all strengths are:

- hypromellose
- starch-maize
- carbomer 941
- silica-colloidal anhydrous
- magnesium stearate

## **Manufacturer**

Sifrol ER tablets are made in Germany and supplied in Australia by:

**BOEHRINGER INGELHEIM PTY LIMITED**

(ABN 52 000 452 308)

78 Waterloo Road

North Ryde NSW 2113

This leaflet was prepared on 16 March 2010.

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