

Pramipexole (Sifrol and Sifrol ER) for Parkinson's disease

This *Medicine Update* is for people who are using pramipexole or are thinking about starting it.

Summary

Pramipexole is a new medicine to treat Parkinson's disease. Like other medicines for Parkinson's disease, it treats the symptoms but does not cure it.

Pramipexole can be taken on its own by people who are just starting treatment for Parkinson's disease. In the later stages it may be prescribed in addition to a medicine called levodopa.

In the early stages of Parkinson's disease, you and your doctor may be able to choose between pramipexole and medicines like levodopa. Levodopa is generally a little more effective than pramipexole at controlling symptoms, but after a few years of taking levodopa uncontrollable twisting and jerking movements are likely to develop. With pramipexole different side effects, like hallucinations and confusion, are more common.

Your choice should take into account your age, and the need to balance control of the symptoms of Parkinson's disease with the potential side effects of the different medicines.

www.nps.org.au/medicineupdate

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Asking the right questions about new medicines

What is Medicine Update?

Medicine Update provides independent information about new medicines and new listings on the PBS. It tells you about the possible benefits and harms of new medicines, who can and can't use them, and some of the other treatment options available.

How to use Medicine Update

Medicine Update is a tool to help you understand your treatment choices and to discuss them with your doctor. *Medicine Update* doesn't describe all possible side effects, precautions, or interactions with other medicines — so you should always read the consumer medicine information (CMI) leaflet (see back page).

Who is it for?

Medicine Update is for anyone who is starting this medicine or thinking of starting it, and their carers.

Where does Medicine Update come from?

Medicine Update is written by the National Prescribing Service Limited (NPS) in consultation with consumers and health professionals. NPS is an independent, non-profit, government-funded organisation.

NPS takes reasonable care to ensure this information is accurate and up-to-date at the time of creation. It is for your information only and is not medical advice. NPS does not warrant its completeness and excludes liability where permitted by law. We recommend you seek advice from a health professional about your medical condition.

1. What pramipexole is

The active ingredient of this medicine is **pramipexole** (pronounced pram-i-PECKS-ole). It is also known by the brand names **Sifrol** and **Sifrol ER**.

The active ingredient is the chemical in the medicine that makes the medicine work.

Many medicines are known by their brand names as well as by the name of the active ingredient. Some medicines are available under several different brand names.

2. What pramipexole is for

Pramipexole is used to treat the symptoms of Parkinson's disease. Parkinson's disease is a disease of the brain that affects body movement.

Pramipexole is not a cure for Parkinson's disease, nor does it stop the progression of Parkinson's disease.

The main symptoms of Parkinson's disease are:

- muscle stiffness (also known as muscle rigidity)
- tremor, or shakiness, especially of the hands
- difficulty starting to move or walk
- slowing down of movement.

All these symptoms tend to fluctuate throughout the day and will affect people differently.

3. Who can take pramipexole

You can take pramipexole if you have Parkinson's disease. You can take it on its own, or in addition to another medicine called levodopa.

Pramipexole may also be used for another condition known as restless legs syndrome. Restless legs syndrome is not discussed in this leaflet.

Talk with your doctor about all of the treatment options for Parkinson's disease.

4. How to take pramipexole

You should discuss how to take pramipexole with your doctor and make sure you have written instructions to refer to later.

There are two different forms of pramipexole

One form — Sifrol — needs to be taken 3 times a day. These are sometimes called immediate-release tablets.

The other form — Sifrol ER — is taken once a day. The ER stands for extended-release, which means that the medicine is long-acting.

Be aware: both Sifrol and Sifrol ER are available in several strengths (doses).

4. How to take pramipexole ... *continued*

The different pramipexole tablets look similar. You should check the label on the box carefully to make sure you are taking the right tablet and strength. This is especially important if your prescription changes:

- to a new strength of pramipexole tablet, or
- from immediate-release tablets (Sifrol) to the extended-release tablets (Sifrol ER).

Take pramipexole tablets that you no longer need to your pharmacist for disposal. Ask your doctor or pharmacist if you are not sure.

Taking pramipexole tablets

Both forms of pramipexole can be taken with or without food. But you must not break, crush or chew the extended-release tablets (Sifrol ER).

Usually you will start on a low dose, then gradually increase the dose each week until:

- your symptoms have improved, or
- the side effects are bothering you, or
- you have reached the maximum dose of 4.5 milligrams (not everybody will need to take this much pramipexole).

Your pharmacist will be able to explain the doses to you, and help you to take your pramipexole tablets correctly.

5. When you can take pramipexole

Parkinson's disease usually comes on gradually. It may start with a little stiffness, or a mild tremor, before gradually getting worse. When you have been diagnosed with Parkinson's disease, the important and difficult question is when you should start taking a medicine.

Most people choose to begin treatment when their symptoms start to interfere with their day-to-day activities. The tremor might make it hard to write. Or the stiffness might interfere with daily walks.

Early treatment won't stop the disease progressing, but it might make you feel better and help you to manage on a day-to-day basis.

Pramipexole is one of the medicines that you can start taking when your symptoms begin to be a problem. You can also take it later on, in combination with levodopa.

6. What does pramipexole do?

The symptoms of Parkinson's disease are caused by a lack of dopamine, which is a naturally occurring chemical produced in the brain. When there is too little dopamine, movement is affected.

Pramipexole is a type of medicine known as a dopamine agonist. It works in the brain in a similar way to dopamine. It can help to reduce tremor, muscle stiffness and slowness of movement.

7. Important side effects to consider

All medicines have side effects. Sometimes the side effects are serious but most of the time they are not.

Pramipexole has some side effects that are common. They include:

- sleepiness
- nausea
- constipation
- dizziness when standing
- swelling of the hands, ankles or feet.

These side effects tend to lessen over time.

Pramipexole has other side effects that are less common. They include:

- suddenly falling asleep (a sleep attack). This happens without warning and can be particularly dangerous when driving
- compulsive behaviours such as gambling, shopping or an irresistible urge to do something pointless over and over again
- increased sexual urges that can be difficult to resist and may be a problem for you or your partner
- seeing, hearing or feeling things that are not there (also known as hallucinations)
- difficulty thinking clearly (confusion).

You should tell your doctor as soon as possible if you or your family notice any of these side effects. But do not stop taking your medicine suddenly without consulting your doctor — this could cause problems.

For a list of possible side effects, see the consumer medicine information (CMI) leaflets for Sifrol and Sifrol ER.

Ask your doctor about the possible side effects of this medicine before you take it.

Always tell your doctor about any changes to your condition if you are taking a new medicine.

You can also discuss side effects with a pharmacist, by calling the Adverse Medicines Event (AME) Line on 1300 134 237 (Mon-Fri, 9am-5pm).

8. What else you should know about pramipexole

There are some medicines that cannot be taken with pramipexole and others that should only be taken after you have talked to your doctor about it.

You should tell your doctor about all the medicines you take, including any you get from a pharmacy, supermarket or health food store.

If you are already taking levodopa when you start taking pramipexole, your doctor may need to adjust your dose of levodopa

You can find out more about pramipexole in the consumer medicine information leaflets (see back page).

9. Other medicines available for Parkinson's disease

The two main types of medicine used to treat Parkinson's disease are **dopamine agonists** — like pramipexole — and **levodopa**. They can be taken on their own, or in combination.

Examples of **dopamine agonists** include pramipexole (Sifrol and Sifrol ER), bromocriptine (Kripton, Parlodel), cabergoline (Bergoline, Cabaser), pergolide (Permax) and rotigotine (Neupro).

Levodopa has a number of brand names, including Kinson, Levohexal, Madopar, Sinemet and Stalevo. Levodopa tablets and capsules also contain medicines to help the levodopa work better.

There are other types of medicines that are less commonly used to treat Parkinson's disease, but these are not discussed in this leaflet.

How dopamine agonists and levodopa are used

Dopamine agonists may be the first medicine to be used in younger people (for example those in their sixties or younger) in the early stage of Parkinson's disease. In older people, or those who have had Parkinson's disease for longer, dopamine agonists can be added if levodopa is not working as well as it used to.

Levodopa is the medicine most commonly used to treat Parkinson's disease. Most people will take levodopa at some stage, especially when their symptoms become more severe.

Side effects of dopamine agonists and levodopa

Many of the side effects of dopamine agonists and levodopa are very similar. The main side effects of both of these types of medicine are:

- sleepiness
- nausea and vomiting
- constipation
- dizziness when standing
- trouble sleeping
- swelling of the hands, ankles or feet
- falling asleep without warning (sleep attack).

But there are some differences in side effects between dopamine agonists and levodopa. These include:

- **hallucinations and confusion.** Hallucinations and confusion are more likely with dopamine agonists than levodopa, especially in older people with Parkinson's disease
- **compulsive behaviour.** This is a potentially serious, but not very common, side effect that has happened with dopamine agonists more than with levodopa
- **problems with the heart or lungs.** Some dopamine agonists can cause problems with the heart or lungs. If you are prescribed one of these medicines, your doctor will check regularly for these side effects. Levodopa does not cause these problems and, so far, pramipexole does not appear to cause them

9. Other medicines available for Parkinson's disease ... *continued*

- **uncontrollable movements.** Almost everybody who takes levodopa will eventually develop movements they can't control. These include jerking, twisting and dancing movements of the arms and legs (called dyskinesias). These may begin within a year or two of starting levodopa, or they may come on more slowly. These side effects can be distressing and difficult to manage, although they may improve by lowering the dose of levodopa. Dopamine agonists do not cause these movement problems
- **'wearing off'.** After taking levodopa for a few years the effect of each dose starts to 'wear off' before the next dose is due. This means that the muscle stiffness, tremor and slow movements of Parkinson's disease can reappear, sometimes quite strongly. These symptoms improve or disappear again when the next dose of levodopa is taken. Your doctor might be able to help you manage the 'wearing off' effect by adjusting the time or dose of your levodopa.

10. How to decide between pramipexole and other medicines

In the early stage of Parkinson's disease the choice between a dopamine agonist — like pramipexole — or levodopa is not a simple one. Either type of medicine may be suitable, so the choice will depend on your own situation and preferences.

In a clinical trial that included people with the early stage of Parkinson's disease, levodopa controlled the symptoms slightly better than pramipexole. Levodopa also produced fewer side effects like sleepiness, hallucinations and swelling of the hands or feet. However, after two years, more people taking levodopa developed twisting and jerking movements they couldn't control and had 'wearing off' effects (see section 9).

For people with the early stage of Parkinson's disease — particularly those in their sixties or younger — starting out with pramipexole or another dopamine agonist is an option. By starting with pramipexole, they may be able to delay treatment with levodopa, and in turn delay the uncontrollable movements that it can cause.

However, you need to be aware that pramipexole, or another dopamine agonist, might not control your symptoms as well as levodopa does. And dopamine agonists have their own side effects to consider (see section 9).

As Parkinson's disease progresses most people will have to take levodopa to control their symptoms.

People who start out taking levodopa may eventually also take pramipexole or a similar medicine because of the 'wearing off' effect of levodopa.

The choices are not simple — discuss them with your doctor.

Remember that risks and benefits differ between medicines and from person to person.

A clinical trial is a research study conducted with patients, which compares one treatment with one or more other treatments, to assess its effectiveness and safety.

11. What does pramipexole cost?

The full cost of pramipexole to the Australian Government varies depending on the strength of the tablets and the size of the pack. The costs are as follows:

Immediate-release pramipexole (Sifrol)

- \$11.74 for 0.125 milligram pramipexole tablets (pack size 30 tablets)
- \$41.27 for 0.25 milligram pramipexole tablets (pack size 100 tablets)
- \$152.14 for 1 milligram pramipexole tablets (pack size 100 tablets).

Extended-release pramipexole (Sifrol ER)

- \$22.39 for 0.375 milligram pramipexole extended release tablets (pack size 30 tablets)
- \$37.84 for 0.75 milligram pramipexole extended release tablets (pack size 30 tablets)
- \$66.51 for 1.5 milligram pramipexole extended release tablets (pack size 30 tablets).
- \$137.56 for 3 milligram pramipexole extended release tablets (pack size 30 tablets)
- \$203.13 for 4.5 milligram pramipexole extended release tablets (pack size 30 tablets).

If you get pramipexole through the Pharmaceutical Benefits Scheme (PBS), the Australian Government pays most of the cost and you will pay only a part, called the co-payment.

At the time of publication, the co-payment for people who are eligible to get pramipexole through the PBS was:

- \$33.30 for people without a concession card
- \$5.40 for concession card holders.

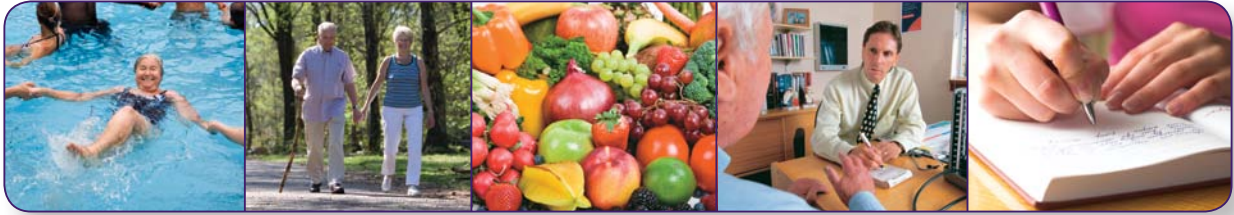
If you are not eligible to get pramipexole through the PBS, you would need to pay the full price for a prescription.

Most medicines prescribed by your doctor are covered by the PBS. This means that the Australian Government pays part of the cost of your medicine.

You will need to pay the full price if the medicine is not available on the PBS, or is not available on the PBS for your specific condition.

For more information see www.pbs.gov.au

12. Other ways to help Parkinson's disease



A healthy lifestyle is important for everyone, but for people with Parkinson's disease it is essential to have a balanced and nutritious diet with plenty of fibre and fluids. Regular exercise is needed to help maintain muscles and joints.

Diet

It is common for people with Parkinson's disease to lose weight as they find eating difficult and they may also lose their appetite. You may find smaller more frequent snacks easier to manage than three main meals. High calorie foods such as milkshakes and desserts can help.

Constipation can also be a problem, which is why high fibre foods and plenty of water are particularly important.

A small number of people taking levodopa may find a meal containing a lot of protein reduces the effectiveness of the medicine. Although this is not common, you should discuss the possibility with your doctor.

Exercise

Exercise is good for everyone and is especially important for people with Parkinson's disease as their muscles and joints tend to get stiff and rigid.

Activities such as swimming, aqua-aerobics, hydrotherapy, dancing, gardening, tennis, golf, bowls, walking, yoga, tai chi or a gym routine are particularly suitable.

Exercise can also provide a chance to socialise. And it can help relieve depression.

If you are unsure about the suitability or safety of any exercise you want to do, you should discuss it with your doctor or ask for a referral to a physiotherapist.

Support therapies and services

As Parkinson's disease progresses, physiotherapists, occupational therapists and speech therapists can help with strategies and aids to maximise independence.

These specialists can help with specific exercises, education and retraining to improve coordination, balance and movement.

For more information about Parkinson's disease visit www.parkinsons.org.au or call (02) 6278 8916.

You could also get information and help from the Independent Living Centre. Visit their website, www.ilc.com.au, for contact details for your state or territory organisation.

Where to find out more information

Read the consumer medicine information (CMI) leaflet

The CMI for Sifrol or Sifrol ER will tell you:

- who should not use the medicine
- which medicines should not be used at the same time (medicine interactions)
- how to take the medicine
- most of the possible side effects
- the ingredients.

You can get the CMI leaflet for Sifrol or Sifrol ER from:

- your doctor or pharmacist
- CMI search on the NPS website
- Boehringer Ingelheim, the manufacturers of Sifrol (pramipexole), on 1800 226 315.

Information over the phone

NPS works with *healthdirect Australia* to provide consumers with information on medicines.

To get information about pramipexole call **1300 MEDICINE** (1300 633 424) from anywhere in Australia for the cost of a local call (excluding mobiles). Service is available Monday to Friday 9am–5pm EST except NSW public holidays.

To report a side effect with pramipexole

Call the **Adverse Medicines Event (AME)** Line on 1300 134 237 (Mon–Fri, 9am–5pm EST).

The AME Line lets you report and discuss side effects that might be related to your medicine. The side effects of your medicine — but not your personal details — are reported to the Australian medicines regulatory agency (the Therapeutic Goods Administration or TGA for short). The information helps to improve the safe use of medicines.

For more information about the AME Line visit www.nps.org.au/consumers

More about taking medicines

For more information on how new medicines are tested and approved in Australia see the NPS factsheet *New medicines: are they always better?* at www.nps.org.au/consumers/publications/factsheets

More information on understanding side effects is available from www.asmi.com.au

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www.nps.org.au/consumers

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