

BERGOLINE

contains the active ingredient cabergoline

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about BERGOLINE.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking BERGOLINE against the benefits they expect it will have for you.

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

Keep this leaflet with your medicine. You may need to read it again.

What BERGOLINE is used for

BERGOLINE is used in the management of Parkinson's disease. This is a disease of the brain affecting movement. The main symptoms are tremor, slowing of movements, partial facial paralysis, weakness and a shuffling unbalanced walk. BERGOLINE helps to reduce these symptoms and to improve your ability to do your normal, everyday tasks.

Parkinson's disease is associated with the loss of a chemical called dopamine in the brain. Dopamine helps the brain to control muscular movement.

BERGOLINE belongs to a group of medicines called dopamine agonists. It works by mimicking the actions of dopamine in the brain.

Your doctor may have prescribed BERGOLINE for another reason. Ask your doctor if you have any

questions about why BERGOLINE has been prescribed for you.

BERGOLINE is not recommended for use in children, as there have been no studies of its effects in children.

BERGOLINE is available only with a doctor's prescription.

There is no evidence that BERGOLINE is addictive.

Before you take BERGOLINE

When you must not take it

Do not take BERGOLINE if you are allergic to medicines containing cabergoline, ergot alkaloid medicines, or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, wheezing or shortness of breath.

Do not take BERGOLINE if you have or have had:

- any scarring or thickening of the lungs with shortness of breath
- any evidence of heart valve disorder
- any swelling or inflammation around the heart or lungs
- any abnormal formation of tissue outside the stomach wall.

Your doctor will do some tests before prescribing BERGOLINE to check if you have any of the above conditions. These may include chest x-rays, physical examinations, blood test and heart monitoring.

Do not take BERGOLINE if you are pregnant or plan to become pregnant.

BERGOLINE may affect your developing baby if you take it during pregnancy.

Do not take BERGOLINE if the expiry date (Exp.) printed on the pack has passed.

Do not take BERGOLINE if the packaging is torn or shows signs of tampering.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives. Tell your doctor if you have had an unusual or allergic reaction to other anti-Parkinson drugs.

Tell your doctor if you plan to become pregnant.

Tell your doctor if you are breastfeeding or intend to breastfeed. BERGOLINE prevents the flow of breast milk.

Tell your doctor if you have, or have had, any medical conditions, especially the following:

- liver problems
- lung disease or problems with your breathing
- heart problems including chest pain, a recent heart attack
- Raynaud's syndrome (problems with circulation in the fingers and toes causing the skin colour to turn pale or blue)
- ulcers or bleeding from the stomach or intestine
- mental illness
- low blood pressure.

Your doctor may want to take special care if you have any of these conditions.

If you have not told your doctor or pharmacist about any of the

above, tell them before you start taking BERGOLINE.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may be affected by BERGOLINE, or may affect how well it works. These include:

- medicines used to treat mental illness
- medicines used to treat high blood pressure
- metoclopramide, a medicine used to treat nausea
- medicines called macrolide antibiotics used to treat bacterial infections such as erythromycin
- other medicines used to treat Parkinson's disease.

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking BERGOLINE.

How to take BERGOLINE

How much to take

The dose varies from patient to patient.

Your doctor will tell you how many tablets to take. The usual starting dose is 0.5 to 1 mg a day. Your doctor will gradually increase your dose over several weeks.

The maximum recommended dose for BERGOLINE is 3 mg a day.

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

How to take BERGOLINE

Swallow the tablets with a glass of water, preferably with meals.

Taking BERGOLINE with a meal will lessen any side effects you may experience.

Take BERGOLINE at about the same time each day.

Taking it about the same time each day will have the best effect. It may also help you remember when to take it.

If you forget to take BERGOLINE

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

Do not take a double dose to make up for the dose you missed.

If you are not sure what to do, ask your doctor or pharmacist.

How long to take BERGOLINE for

To properly control your condition, BERGOLINE must be taken every day.

Keep taking BERGOLINE for as long as your doctor recommends.

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 take too much BERGOLINE (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think that you

or anyone else may have taken too much BERGOLINE. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much BERGOLINE, you may have nausea, vomiting, stomach pains, dizziness, low blood pressure, confusion or hallucinations.

While you are taking BERGOLINE

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking BERGOLINE.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking BERGOLINE.

Visit your doctor regularly so he/she can check on your progress.

It is important that your doctor do some tests every 6 to 12 months while you are being treated with BERGOLINE to make sure the medicine is working and to prevent unwanted side effects. For example, chest x-rays, physical examinations, blood tests and heart monitoring.

If you become pregnant while taking this medicine, tell your doctor immediately.

Things you must not do

Do not stop taking BERGOLINE, or lower the dose unless your doctor tells you to, even if you feel better.

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects.

Do not use BERGOLINE to treat any other conditions unless your doctor tells you to.

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

Things to be careful of

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

BERGOLINE may cause irregular movements, dizziness or light-headedness in some people, especially during the first few days of taking it. If any of these occur, do not drive, operate machinery or do anything else that requires being alert.

Some people taking BERGOLINE may experience sleepiness and/or sudden onset of sleep. If you are affected, you should avoid driving or operating machinery.

Be careful getting up from a sitting or lying position.

Dizziness, light-headedness or fainting may occur, especially when you get up quickly. Getting up slowly may help.

Be careful of drinking alcohol while taking BERGOLINE.

The effect of drinking alcohol while taking BERGOLINE is not known.

Side effects

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

Like all other medicines, BERGOLINE may have unwanted side effects in some people. 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 this list of possible side effects.

You may not experience any of them.

If you are over 65 years of age you may have an increased chance of getting side effects.

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:

- problems with sleeping, sleepiness, sudden onset of sleep
- abnormal movements, increased movements
- increased sweating
- lower stomach pain
- diarrhoea, constipation
- nausea, vomiting
- heartburn, indigestion, sore stomach
- dizziness, fainting
- headache
- weakness, unusual tiredness
- swelling of hands or feet
- leg cramps
- back pain
- unusual hair loss or thinning
- changes in behaviour such as gambling, increased sex drive, shopping, eating, medication use, repetitive purposeless activity.

Changes in behaviour may have serious financial and social consequences.

Tell your doctor as soon as possible if you notice any of the following:

- hallucinations or irrational thoughts or ideas
- confusion, anxiousness
- irregular heart beat
- any breathing problem
- persistent cough.

These are serious side effects which may require medical attention.

If any of the following happen while taking BERGOLINE, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- sudden signs of allergy such as rash, itching or hives, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or difficulty breathing.
- chest pain with shortness of breath.

These are very serious side effects. You may need urgent medical attention or hospitalisation.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

After using BERGOLINE

Storage

Keep BERGOLINE where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep your tablets in the bottle until it is time to take them.

If you take the tablets out of the bottle, they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C and protected from light.

Do not store BERGOLINE or any other medicine in the bathroom or near a sink.

Do not leave BERGOLINE in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking BERGOLINE, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

BERGOLINE comes in two strengths of tablets:

- BERGOLINE 1 – A white to off-white, oval-shaped tablet embossed with 'C | 1' on one side and 'partial score ∩' on the other side
- BERGOLINE 2 – A white to off-white, capsule-shaped tablet embossed with 'CE | 2' on one

side and 'partial score >>' on the other side
Each bottle contains 30 tablets.

Ingredients

The active ingredient in BERGOLINE is cabergoline.

- each BERGOLINE 1 tablet contains 1 mg of cabergoline
- each BERGOLINE 2 tablet contains 2 mg of cabergoline

The tablets also contain:

- leucine
- lactose.

The tablets do not contain gluten, sucrose, tartrazine or any other azo dyes.

Supplier

Sigma Pharmaceuticals (Australia) Pty Ltd
96 Merrindale Drive
Croydon Vic 3136
Tel: 03 - 9839 2800

Australian registration numbers:
BERGOLINE 1 - AUST R 132562
BERGOLINE 2 - AUST R 132563

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