

Cabergoline

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Cabaser. It does not contain all the available information and it does not take the place of talking to your doctor or pharmacist.

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

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

Keep this leaflet with your medicine.

You may need to read it again.

What Cabaser is used for

Cabaser is used in the management of the signs and symptoms of Parkinson's disease. This is a disease of the brain affecting movement. The main symptoms are tremor, rigid posture, slow movements and a shuffling, unbalanced walk. Cabaser helps to reduce these symptoms and to improve your ability to do your normal, everyday tasks.

Parkinson's disease is caused by the brain not making enough of a chemical called dopamine. Dopamine helps the brain to control muscle movement.

Cabaser belongs to a group of medicines called dopamine agonists. It works by increasing the effects of dopamine.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription and treatment should be started only by your specialist.

Before you take Cabaser

CABASER MAY CAUSE HEART VALVE PROBLEMS OR MAY AFFECT YOUR LUNG AND KIDNEY FUNCTION.

BEFORE STARTING TREATMENT WITH CABASER YOUR DOCTOR WILL NEED TO DO SOME TESTS, TO DETECT ANY UNDERLYING HEART, LUNG OR KIDNEY DISEASE.

These tests include chest x-rays, physical examinations, blood tests and heart monitoring.

Your doctor will repeat these tests regularly while you are on Cabaser.

WHILE TAKING CABASER BE SURE TO TELL YOUR DOCTOR ABOUT ANYTHING THAT IS MAKING YOU FEEL UNWELL, SUCH AS DIFFICULTY IN BREATHING, CHEST PAIN OR SWELLING OF YOUR HANDS OR FEET.

When you must not take it

Do not take Cabaser 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 scar tissue outside the stomach wall.

Do not take Cabaser if you have an allergy to:

- any medicine containing cabergoline
- any other ergot alkaloid
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- · wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not give this medicine to a child.

Safety and effectiveness in children 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.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

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

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

Tell your doctor if you are pregnant or plan to become pregnant.

Your doctor will discuss with you the risks and benefits involved.

It is recommended that women who plan to become pregnant stop taking Cabaser at least one month before becoming pregnant.

Tell your doctor if you are breast-feeding.

Your doctor will discuss with you the risks and benefits involved. It is possible that Cabaser will prevent the production of milk.

If you have not told your doctor about any of the above, tell him/ her before you start taking Cabaser.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including:

- all prescription medicines
- all medicines, vitamins, herbal supplements or natural therapies you buy without a prescription from a pharmacy, supermarket, naturopath or health food shop.

Some medicines may be affected by Cabaser or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you.

Tell your doctor or pharmacist if you are taking any of the following:

- medicines used to lower your blood pressure
- other medicines used for Parkinson's disease
- medicines used to treat mental illness
- metoclopramide, a medicine used to treat nausea
- macrolide antibiotics such as erythromycin.

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

How to take Cabaser

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

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box/bottle, ask your doctor or pharmacist for help.

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 half to one 1 mg tablet (0.5 mg to 1 mg) a day. Your doctor will gradually increase your dose over several weeks. The recommended maintenance dose is 2 mg to 3 mg a day.

Follow all instructions from your doctor and pharmacist carefully.

How to take it

Swallow the tablets whole with a full glass of water.

If your doctor has prescribed half a tablet, break the tablet in half along the scoreline.

When to take it

Take your medicine once a day, preferably with meals.

Taking it with food will lessen any side effects you may experience.

Take your medicine 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.

If you are not sure of how to take Cabaser, ask your doctor or pharmacist.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

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 forget to take it

If you forget to take one or more of your Cabaser tablets, take your next tablet at the normal time it is due.

Do not take a double dose to make up for the dose that you 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 (overdose)

Immediately telephone your doctor or the Poisons Information Centre (131 126) for advice or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much Cabaser. Do this even if there are no signs of discomfort or poisoning.

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You may need urgent medical attention.

Symptoms of an overdose may include:

- nausea
- vomiting
- stomach complaints
- feeling dizzy
- · confusion
- hallucinations.

Have the Cabaser bottle or box or this leaflet available to give details if needed.

While you are taking Cabaser

Things you must do

Follow your doctor's requests for tests and report anything unusual to your doctor such as difficulty in breathing, chest pain or swelling of your hands or feet.

Keep all of your doctor's appointments so that your progress can be checked.

It is important that your doctor does some tests every 6 to 12 months while you are taking Cabaser to make sure the medicine is working and to prevent unwanted side effects. These tests may include chest x-rays, physical examinations, blood tests and heart monitoring.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Cabaser.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

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

Things you must not do

Do not take Cabaser to treat any other complaints unless your doctor tells you to.

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

Do not stop taking your medicine or change the dosage without checking with your doctor.

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

Things to be careful of

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

In some people, Cabaser may cause dizziness, light headedness or irregular movements especially during the first days of taking it. Some people may also experience sleepiness and/or sudden onset of sleep. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

See your doctor if you notice changes in your behaviour that result in a strong desire to either gamble, shop, eat or use medicines to excess, or you notice an increase in your sex drive.

Such compulsive behaviours have been seen with some medicines used to treat Parkinson's disease, including Cabaser.

Be careful when drinking alcohol while taking Cabaser.

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

Side effects

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

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

It can be difficult to tell whether side effects are the result of taking Cabaser, effects of your condition or side effects of other medicines you may be taking. For this reason it is important to tell your doctor of any change in your condition.

Do not be alarmed by the following lists of 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...

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- unusual sleepiness, sudden onset of sleep
- abnormal movements, increased movements
- · increased sweating
- diarrhoea, constipation
- · lower stomach pain
- · nausea, vomiting
- · dizziness, fainting
- headache
- weakness, excessive tiredness
- leg cramps
- back pain
- unusual hair loss or thinning
- · aggressive behaviour
- changes in behaviour such as increased sex drive, a compelling desire to gamble, shop, eat or take medicines.

Tell your doctor as soon as possible if...

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 problems
- · chest pain
- · swelling of the hands or feet
- · persistent cough
- · kidney problems
- tenderness around the abdomen (tummy area).

The above list includes serious side effects which may require medical attention.

Go to hospital if...

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital, if you notice any of the following:

- chest pain with shortness of breath
- 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.

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

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people. Some of these side effects (for example, changes in blood pressure, and certain heart, lung and liver conditions) can only be found when your doctor does tests from time to time to check your progress.

Your doctor will do some tests every 6 to 12 months while you are taking Cabaser to help prevent unwanted side effects. For example, chest x-rays, physical examinations, blood

tests and heart monitoring. Such tests can detect leaky and/or narrowed valves of the heart and any scarring or thickening of the lungs.

After taking Cabaser

Storage

Store your tablets in their 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.

Do not store your Cabaser tablets or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the

Heat and dampness can destroy your medicine.

Keep it where children cannot reach it.

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

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Cabaser is available as a tablet in two different strengths, 1 mg and 2 mg.

Cabaser 1 mg - white, oval, both sides concave tablets, one side scored and engraved '7' on the left of the break-line and '01' on the right of it.

Cabaser 2 mg - white, oval, both sides concave tablets, one side scored and engraved '7' on the left of the break-line and '02' on the right of it.

All Cabaser tablets have a score mark which allows the tablet to be broken in half.

Cabaser tablets come in bottles with child-resistant caps and enclosed in an outer cardboard carton.

Each pack contains 30 tablets.

Ingredients

The active ingredient in Cabaser is cabergoline. Each tablet contains either 1 mg or 2 mg of cabergoline.

Cabaser also contains the following inactive ingredients:

- lactose anhydrous
- leucine.

Supplier

Cabaser is supplied in Australia by: Pfizer Australia Pty Ltd ABN 50 008 422 348 38-42 Wharf Road West Ryde NSW 2114 Australia

Toll Free number: 1800 675 229

Australian registration numbers

1 mg AUST R 57360 2 mg AUST R 57367

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