

## **PACKAGE LEAFLET**

### **PATIENT INFORMATION LEAFLET**

#### **CABASER® 1mg and 2mg tablets**

Cabergoline

#### **Read all of this leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **In this leaflet:**

1. What CABASER is and what it is used for
2. Before you take CABASER
3. How to take CABASER
4. Possible side effects
5. How to store CABASER
6. Further information

### **1. WHAT CABASER IS AND WHAT IT IS USED FOR**

CABASER is used to treat the symptoms of Parkinson's Disease.

It is used after your doctor has tried other treatments that have not worked or for people who are already taking other medicines for this illness to help control other symptoms.

The tablets contain the active ingredient Cabergoline which acts in a similar way to a chemical in the body called dopamine. Patients with Parkinson's Disease do not have enough of this chemical.

Cabergoline belongs to a group of medicines called dopamine agonists.

### **2. BEFORE YOU TAKE CABASER**

#### **Do not take CABASER**

- If you are allergic (hypersensitive) to Cabergoline, to other medicines called ergot alkaloids or any of the other ingredients of CABASER listed in section 6 of this leaflet.
- If you will be treated with Cabaser for a long period and have or had fibrotic reactions (scar tissue) affecting your heart.
- If you have been told you have a problem affecting your heart valves.

#### **Take special care with CABASER**

If you have or had fibrotic reactions (scar tissue) affecting your heart, lungs or abdomen. In case you are treated with Cabaser for a long period, your physician will check before starting treatment whether your heart, lungs and kidneys are in good condition. He/she will also have an

echocardiogram (an ultrasound test of the heart) taken before treatment is started and at regular intervals during treatment. If fibrotic reactions occur treatment will have to be discontinued.

Low blood pressure (postural hypotension) can occur following administration of cabaser, particularly during the first few days of taking Cabaser. Care should be taken when taking Cabaser with other drugs known to lower blood pressure.

Tell your doctor if you or your family/carer notices that you are developing urges or cravings to behave in ways that are unusual for you and you cannot resist the impulse, drive or temptation to carry out certain activities that could harm yourself or others. These are called impulse control disorders and can include behaviours such as addictive gambling, excessive eating or spending, an abnormally high sex drive or an increase in sexual thoughts or feelings. Your doctor may need to adjust or stop your dose.

You should inform your doctor if you have or have had any of the following conditions:

- Heart disease.
- Raynaud's syndrome (causing cold hands and feet).
- Severe chest problems (such as pleurisy).
- Liver disease.
- Stomach ulcer, or bleeding from the stomach and intestines.
- Mental illness, in particular psychotic disorders.
- Low blood pressure (postural hypotension) or you are taking any medicines to lower your blood pressure.

### **Taking other medicines**

The effectiveness of CABASER can be reduced by some medicines, these include:

- Drugs used to treat mental illness (e.g. phenothiazines, butyrophenones, thioxanthenes).
- Drugs used to treat sickness (e.g. metoclopramide).

Side-effects may be increased by other medicines, these include:

- Antibiotics (e.g. erythromycin).
- Drugs used for migraines (e.g. ergotamine).

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

### **Taking CABASER with food and drink**

CABASER should be taken after food to help reduce the side-effects.

### **Pregnancy and breast-feeding**

#### **Pregnancy**

If you are pregnant, think you might be pregnant, or trying to become pregnant, tell your doctor before you take CABASER.

#### **Breast-feeding**

Tell your doctor if you are breast-feeding, since this medicine may affect milk production (lactation).

### **Driving and using machines**

CABASER can cause drowsiness (somnolence) and sudden sleepy episodes. Do not drive, use any tools or machines or engage in activities requiring mental alertness or coordination if you experience these symptoms until they have resolved completely.

**Important information about some of the ingredients of CABASER**

CABASER contains lactose, a type of sugar. If you have been told that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

**3. HOW TO TAKE CABASER**

The usual starting dose of CABASER is 1mg daily, preferably taken after food to reduce the side-effects. Your doctor may then increase the dose until he finds a suitable dose to control your symptoms. You should not take more than 3mg of Cabaser in one day.

**If you take more CABASER than you should**

If too many tablets are taken by accident, contact your doctor at once or go to the nearest hospital casualty department.

**If you forget to take CABASER**

If you forget to take your medicine at the usual time, take it as soon as you remember then continue as usual. Do not take a double dose to make up for a missed dose.

**If you stop taking CABASER**

Your doctor will advise you how long to take CABASER. Your condition may return if you stop taking CABASER before you are advised.

If you have any further questions on how to take this product, ask your doctor or pharmacist.

**4. POSSIBLE SIDE-EFFECTS**

Like all medicines, CABASER can cause side-effects, although not everybody gets them.

**Tell your doctor immediately** if you experience any of the following symptoms. These symptoms can be severe:

- Very common side effect (affecting more than one person in ten): heart valve and related disorders e.g. inflammation (pericarditis) or leaking of fluid in the pericardium (pericardial effusion). The early symptoms may be one or more of the following: difficulty breathing, shortness of breath, palpitations (pounding heart), feeling faint, chest pain, back pain, pelvic pain or swollen legs. These may be the first signs of a condition called fibrosis, which can affect the lungs, heart/heartvalves or back.

**You may experience the following side effects:**

- Inability to resist the impulse, drive or temptation to perform an action that could be harmful to you or others, which may include:
  - Strong impulse to gamble excessively despite serious personal or family consequences.
  - Altered or increased sexual interest and behaviour of significant concern to you or to others, for example, an increased sexual drive.
  - Uncontrollable excessive shopping or spending.

- Binge eating (eating large amounts of food in a short time period) or compulsive eating (eating more food than normal and more than is needed to satisfy your hunger).

**Tell your doctor if you experience any of these behaviors; they will discuss ways of managing or reducing the symptoms.**

Other side-effects that may occur are:

- Feeling sick (nausea), being sick (vomiting), indigestion, stomach pain.
- Uncontrolled movements of the limbs, hallucinations, confusion.
- Dizziness, drowsiness, feeling sleepy.
- Chest pain (angina), swelling of the feet and ankles.
- Severe burning pain and skin redness in the hands and feet, low blood pressure, sudden drop in blood pressure on standing.

If any of the side-effects gets serious, or if you notice any side-effects not listed in this leaflet, please tell your doctor or pharmacist.

## **5. HOW TO STORE CABASER**

Keep out of the reach and sight of children.

Do not store above 25 °C.

Do not use CABASER after the expiry date which is stated on the single-dose container tab and the carton after EXP. The expiry date refers to the last day of that month.

CABASER tablets absorb moisture, so you should always replace the cap after taking out your tablets. Do not remove the special granules from the cap, and do not transfer your tablets to another container.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## **6. FURTHER INFORMATION**

### **What CABASER contains**

- The active substance is Cabergoline.
- The other ingredients are lactose and leucine.

### **What CABASER looks like and contents of the pack**

CABASER tablets are white, oval and concave with one side scored and engraved.

The engraving is 7/01 for 1mg tablets and 7/02 for 2mg tablets.

The tablets are packed in glass bottles of 20. Each bottle has a special cap which absorbs moisture.

### **Marketing Authorisation Holder and Manufacturer**

**Marketing Authorisation Holder**

**Pfizer Limited**

Ramsgate Road

Sandwich

Kent

CT13 9NJ

**Manufacturer**

Pharmacia Italia SpA

Ascoli Piceno

Via del Commercio

63046 Marino del Tronto

Italy

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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