



TLPH

## Information for the patient

### Parcini 75mg/100mg/125mg hard capsules

#### palbociclib

This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

#### Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet

1. What Parcini is and what it is used for
2. What you need to know before you take Parcini
3. How to take Parcini
4. Possible side effects
5. How to store Parcini
6. Contents of the pack and other information

#### 1. What Parcini is and what it is used for

Parcini is indicated in combination with letrozole for the treatment of postmenopausal women with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer as initial endocrine-based therapy for their metastatic disease.

It is very important that you also read the leaflets for the other medicines that you will be taking with Parcini. If you have any questions about your medicines, please ask your doctor or pharmacist.

#### 2. What you need to know before you take Parcini

##### Do not take Parcini

- If you are allergic to Parcinior any of the other ingredients of this medicine (listed in section 6 of this leaflet). If this applies to you, tell your doctor immediately.

Before you take Parcini, tell your healthcare provider if you:

- have fever, chills, or any other signs or symptoms of infection.
- have liver or kidney problems.
- have any other medical conditions.
- are pregnant, or plan to become pregnant. Parcini can harm your unborn baby.
  - Females who are able to become pregnant and who take Parcini should use effective birth control during treatment and for at least 2 weeks after stopping Parcini.
  - Talk to your healthcare provider about birth control methods that may be right for you during this time.
  - If you become pregnant or think you are pregnant, tell your healthcare provider right away.
- are breastfeeding or plan to breastfeed. It is not known if Parcini passes into your breast milk. You and your healthcare provider should decide if you will take Parcini or breastfeed. You should not do both.

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Parcini and other medicines may affect each other causing side effects.

Know the medicines you take. Keep a list of them to show your healthcare provider or pharmacist when you get a new medicine.

#### Avoid concurrent use of strong CYP3A inhibitors.

- If patients must be administered a strong CYP3A inhibitor, reduce the Parcini dose to 75 mg/day.
- If the strong inhibitor is discontinued, increase the Parcini dose (after 3–5 half-lives of the inhibitor) to the dose used prior to the initiation of the strong CYP3A inhibitor.

If you are not sure, talk to your doctor or pharmacist.

#### Children and adolescents

Do not give this medicine to children and adolescents under 18 years of age. The use of Parcini in children and adolescents has not yet been studied.

#### Driving and using machines

When taking Parcini, patients have reported tiredness, dizziness, shortness of breath and reduced attention. If you have any of these side effects, do not drive or use any tools or machines.

#### 3. How to take Parcini

- Take Parcini exactly as your healthcare provider tells you.
- Take Parcini with food.
- Swallow Parcini capsules whole. Do not chew, crush or open Parcini capsules before swallowing them.
- Do not take any Parcini capsules that are broken, cracked, or that look damaged.
- Avoid grapefruit and grapefruit products during treatment with Parcini. Grapefruit may increase the amount of Parcini in your blood.
- Do not change your dose or stop taking Parcini unless your healthcare provider tells you.
- If you miss a dose of Parcini or vomit after taking a dose of Parcini, do not take another dose on that day. Take your next dose at your regular time.
- If you take too much Parcini, call your healthcare provider right away or go to the nearest hospital emergency room.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

#### 4. Possible side effects

Parcini may cause serious side effects.

Low red blood cell counts and low platelet counts are common with Parcini.

Call your healthcare provider right away if you develop any of these symptoms during treatment:

- dizziness
- bleeding or bruising more easily
- shortness of breath
- nosebleeds
- weakness

Other common side effects of Parcini include:

- tiredness
- sore mouth
- upper respiratory tract infection
- unusual hair thinning or hair loss
- diarrhea
- decreased appetite
- vomiting
- nausea
- weakness
- numbness or tingling in your arms, hands, legs, and feet

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of Parcini. For more information, ask your healthcare provider or pharmacist.

#### 5. How to store Parcini

- Store Parcini at 68 °F to 77 °F (20 °C to 25 °C).

Keep Parcini and all medicines out of the reach of children.

Medicines are sometimes prescribed for purposes other than those listed in Patient Information leaflet. Do not use Parcini for a condition for which it was not prescribed. Do not give Parcini to other people, even if they have the same symptoms you have. It may harm them.

If you would like more information, talk with your healthcare provider.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

#### **6. Contents of the pack and other information**

##### **What Parcini contains**

##### **Parcini capsules for oral administration contain 125 mg, 100 mg, or 75 mg of palbociclib**

Active ingredient: palbociclib

Inactive ingredients: Microcrystalline cellulose, lactose monohydrate, sodium starch glycolate, colloidal silicon dioxide, magnesium stearate, and hard gelatin capsule shells.

Light orange, light orange/caramel and caramel opaque capsule shells contain: gelatin, red iron oxide, yellow iron oxide, and titanium dioxide.

The following pack sizes are available: outer cartons containing 1 bottle of 21 capsules .

Each bottle contains a silica gel desiccant (drying agent) that must be kept in the bottle to help protect your capsules. The silica gel desiccant is contained in a separate sachet or canister and should not be swallowed.

##### **Marketing Authorisation Holder**

Tongmeng(Lao) Pharmaceutical and Food Co., Ltd  
Rd13 South,31km,Ban Naphasuk,Saithany District  
Vientiane  
Lao PDR

##### **Manufacturer**

Tongmeng(Lao) Pharmaceutical and Food Co., Ltd  
Rd13 South,31km,Ban Naphasuk,Saithany District  
Vientiane  
Lao PDR



TLPH