

Package leaflet: Information for the patient

Palbociclib Capsules



WEBACE 75 mg hard gelatin capsules
WEBACE 100 mg hard gelatin capsules
WEBACE 125 mg hard gelatin capsules

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What WEBACE is and what it is used for
2. What you need to know before you take WEBACE
3. How to take WEBACE
4. Possible side effects
5. How to store WEBACE

1. What WEBACE is and what it is used for

WEBACE is an anticancer medicine containing the active substance palbociclib.

Palbociclib works by blocking proteins called cyclin-dependent kinase 4 and 6, which regulate cell growth and division. Blocking these proteins can slow down growth of cancer cells and delay the progression of your cancer.

WEBACE is used to treat patients with certain types of breast cancer (hormone receptor-positive, human epidermal growth factor receptor 2-negative) which have spread beyond the original tumour and/or to other organs. It is given together with aromatase inhibitors or fulvestrant, which are used as hormonal anticancer therapies.

2. What you need to know before you take WEBACE Do not take WEBACE

- if you are allergic to palbociclib or any of the other ingredients of this medicine.
- use of preparations containing St. John's Wort, a herbal product used to treat mild depression and anxiety, should be avoided while you are taking WEBACE.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking WEBACE.

WEBACE may reduce the number of your white blood cells and weaken your immune system. Therefore, you may be at greater risk of getting an infection while you are taking WEBACE.

Tell your doctor, pharmacist or nurse if you experience signs or symptoms of an infection, such as chills or fever.

You will have regular blood tests during treatment to check whether WEBACE affects your blood cells (white blood cells, red blood cells, and platelets).

WEBACE may cause severe or life-threatening inflammation of the lungs during treatment that can lead to death. Tell your healthcare provider right away if you have any new or worsening symptoms including:

- difficulty breathing or shortness of breath
- dry cough
- chest pain

Children and adolescents

WEBACE is not to be used in children or adolescents (under 18 years of age).

Other medicines and WEBACE

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines.

WEBACE may affect the way some other medicines work. In particular, the following may increase the risk of side effects with WEBACE:

- Lopinavir, indinavir, nelfinavir, ritonavir, telaprevir, and saquinavir used to treat HIV infection/AIDS.
- Clarithromycin and telithromycin antibiotics used to treat bacterial infections.
- Voriconazole, itraconazole, ketoconazole, and posaconazole used to treat fungal infections.
- Nefazodone used to treat depression.

The following medicines may have increased risk of side effects when given with WEBACE:

- Quinidine generally used to treat heart rhythm problems.
- Colchicine used to treat gout.
- Pravastatin and rosuvastatin used to treat high cholesterol levels.
- Sulfasalazine used to treat rheumatoid arthritis.
- Alfentanil used for anaesthesia in surgery; fentanyl used in pre-procedures as a pain reliever as well as an anaesthetic.
- Cyclosporine, everolimus, tacrolimus, and sirolimus used in organ transplantation to prevent rejection.
- Dihydroergotamine and ergotamine used to treat migraine.
- Pimozide used to treat schizophrenia and chronic psychosis.

The following medicines may reduce the effectiveness of WEBACE:

- Carbamazepine and phenytoin, used to stop seizures or fits.
- Enzalutamide to treat prostate cancer.
- Rifampin used to treat tuberculosis (TB).
- St. John's Wort, a herbal product used to treat mild depression and anxiety.

WEBACE with food and drink

Avoid grapefruit and grapefruit juice while you are taking WEBACE as it may increase the side effects of WEBACE.

Pregnancy and breast-feeding and fertility

You should not use WEBACE if you are pregnant. You should avoid becoming pregnant while taking WEBACE.

Discuss contraception with your doctor if there is any possibility that you or your partner may become pregnant. If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Women of childbearing potential who are receiving this medicinal product, or their male partners should use adequate contraceptive methods (e.g., double-barrier contraception such as condom and diaphragm). These methods should be used during therapy and for at least 3 weeks after completing therapy for females and for at least 14 weeks for males.

Breast-feeding

You should not breast-feed while taking WEBACE. It is not known if WEBACE is excreted in breast milk.

Fertility

Palbociclib may decrease fertility in men.

Therefore, men may consider sperm preservation before taking WEBACE.

Driving and using machines

Tiredness is a very common side effect of WEBACE. If you feel unusually tired, take special care when driving or using machines.

WEBACE contains lactose and sodium

This medicine contains lactose (found in milk or dairy products). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say it is essentially 'sodium-free'.

3. How to take WEBACE

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is 125 mg of WEBACE taken once a day for 3 weeks followed by 1 week without taking WEBACE. Your doctor will tell you how many capsules of WEBACE to take.

If you experience certain side effects while you are taking WEBACE (see section 4 "Possible side effects"), your doctor may lower your dose or stop treatment, either temporarily or permanently. The dose may be lowered to one of the other available strengths 100 mg or 75 mg.

Take WEBACE once a day at about the same time every day with food, preferably a meal.

Swallow the capsule whole with a glass of water. Do not chew or crush the capsules. Do not open the capsules.

If you take more WEBACE than you should

If you have taken too much WEBACE, see a doctor or go to a hospital immediately. Urgent treatment may be necessary. Take the carton and this leaflet, so that the doctor knows what you have been taking.

If you forget to take WEBACE

If you miss a dose or vomit, take your next dose as scheduled. Do not take a double dose to make up for the forgotten capsules.

If you stop taking WEBACE

Do not stop taking WEBACE unless your doctor tells you to. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them: Contact your doctor immediately if you have any of these symptoms:

- fever, chills, weakness, shortness of breath, bleeding, or easy bruising which could be a sign of a serious blood disorder.
- difficulty breathing, dry cough or chest pain which could be a sign of inflammation of the lungs.

Other side effects with WEBACE may include:

Very common side effects (may affect more than 1 in 10 people):

Infections

Reduction in white blood cells, red blood cells, and blood platelets

Feeling of tiredness

Decreased appetite

Inflammation of the mouth and lips (stomatitis), nausea,

vomiting, diarrhoea

Rash

Hair loss

Weakness

Fever

Abnormalities in liver blood tests

Dry skin

Common side effects (may affect up to 1 in 10 people):

Fever with a drop in the white blood cell count (febrile neutropenia)

Blurred vision, increased tearing, dry eye

Alteration in taste (dysgeusia)

Nosebleed

Uncommon side effects (may affect up to 1 in 100 people):

Inflammation of the skin causing red scaly patches and possibly occurring together with pain in the joints and fever (Cutaneous Lupus Erythematosus [CLE]).

5. How to store WEBACE

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the bottle or blister and carton after "EXP". The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not use this medicine if you notice that the pack is damaged or shows signs of tampering.

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 protect the environment.

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