

## Everolimus (Afinitor)

1. What is everolimus?
2. Who might be offered everolimus?
3. How does everolimus work?
4. How is everolimus given?
5. Common side effects of everolimus
6. Less common side effects of everolimus
7. Rare side effects of everolimus
8. Blood clots
9. Sex and contraception
10. Travel and vaccinations

## 1. What is everolimus?

Everolimus is a targeted (biological) therapy. This group of drugs block the growth and spread of cancer. They target and interfere with processes in the cells that cause cancer to grow. Everolimus is the generic, non-branded name of the drug, but you may hear it called by its brand name, Afinitor.

## 2. Who might be offered everolimus?

Everolimus may be offered to post-menopausal women with ER positive, HER2 negative locally advanced or secondary breast cancer whose breast cancer has come back during or after taking hormone therapy drugs such as letrozole or anastrozole.

Research is continuing to look at the benefits of giving everolimus to other groups of women (for example, women with HER2 positive secondary breast cancer).

### 3. How does everolimus work?

Everolimus belongs to a group of drugs called mTOR inhibitors. mTOR is a protein that affects how cancer cells divide and grow. Everolimus works by blocking mTOR, which helps to stop or slow down the growth of the cancer.

### 4. How is everolimus given?

Everolimus is given as a tablet once a day, with or without food, alongside the hormone therapy drug exemestane. You will be given everolimus as an outpatient.

It's recommended that you avoid eating grapefruit or drinking grapefruit juice while taking everolimus, as it can stop it working properly. If you'd like to know more about this you can speak to your specialist team.

### 5. Common side effects of everolimus

Like any treatment, everolimus can cause side effects. Everyone reacts differently to drugs and some people have more side effects than others. These side effects can usually be controlled and those described here will not affect everyone.

Because it's given with exemestane, you may also experience side effects from that drug as well.

If you're concerned about any side effects, regardless of whether they are listed here, talk to your specialist team as soon as possible.

#### Risk of infection

When the white blood cells fall below a certain level, it's known as neutropenia. Not having enough white blood cells can increase the risk of getting an infection. You may need to be treated with antibiotics or other drugs that help produce more white blood cells.

**Contact your hospital immediately if:**

- **you have a high temperature (over 37.5°C) or low temperature (under 36°C), or whatever your specialist team has advised**
- **you suddenly feel unwell, even with a normal temperature**

- **you have any symptoms of an infection, for example a sore throat, a cough, a need to pass urine frequently or feeling cold and/or shivery**

## **Sore mouth and taste change**

Your mouth may become sore or dry and you may get ulcers. You may be given mouthwash to use to reduce soreness of the mouth and gums and to try to stop mouth ulcers developing. Good mouth hygiene is very important during treatment. It's advisable to see your dentist for a dental check-up before your treatment begins. Check with your specialist before having any dental work done.

Your taste can change and some food may taste different (for example more salty, bitter or metallic). It can be helpful to experiment with different types of food to find the ones you can eat.

## **Fatigue (extreme tiredness)**

It's common to feel extremely tired during your treatment. There are different ways of coping with and managing fatigue. You can speak to your specialist team or contact our Helpline on 0808 800 6000 for information and support.

## **Skin changes**

You may get a rash and your skin may be itchy. Let your doctor or nurse know if you have any skin changes as they can prescribe creams or drugs to help.

## **Diarrhoea or constipation**

You may have diarrhoea or constipation but your specialist or GP can prescribe medicine to help control it. Contact your specialist team if you have four or more episodes of diarrhoea within a 24-hour period.

## **Shortness of breath and coughing**

Everolimus can cause changes to the lungs. Let your doctor or nurse know if you start to feel breathless or develop a cough.

## **Raised blood glucose levels (hyperglycaemia)**

You may be unaware of changes to your blood glucose levels, but you will have regular blood tests to check these while taking everolimus.

## **Bruising and bleeding**

Everolimus can reduce the number of platelets (which help the blood to clot). You may bruise more easily, have nosebleeds or your gums may bleed when you brush your teeth. Tell your specialist team if you notice any of these symptoms.

## **Anaemia**

Having too few red blood cells is called anaemia. If you feel particularly tired, breathless or dizzy, let your specialist team know. A blood transfusion may be necessary during your treatment if the number of red blood cells falls significantly.

## **High cholesterol**

Everolimus may cause your cholesterol levels to increase. You will have regular blood tests while taking everolimus to check your cholesterol levels.

## **Nausea and vomiting**

You may experience nausea (feeling sick) and vomiting (being sick), but most people will not actually be sick. You'll be prescribed anti-sickness drugs to take home to reduce nausea or stop it happening. If you continue to feel sick or vomit, tell your specialist team as they may be able to change your anti-sickness drugs.

# **6. Less common side effects of everolimus**

## **Allergic reaction**

If you have an allergic reaction to everolimus, it is more likely to happen the first time you have the treatment. Before your treatment starts, you'll be given drugs to reduce the risk of an allergic reaction.

You will be monitored closely during your treatment so that any reaction can be dealt with immediately. You should contact your hospital if you notice any of the following symptoms:

- itchy red bumps on the skin
- swelling in your lips, tongue or throat
- breathlessness, wheezing, a bad cough or sudden difficulty breathing
- tight chest or chest pain

## **Kidney problems**

Everolimus can affect how well your kidneys work. You'll have regular blood tests while taking it to check how well they are working. If you have difficulty passing urine let your specialist team or GP know.

## **Liver changes**

Everolimus can also affect how the liver works. You'll have regular blood tests to check that your liver is working properly. Sometimes treatment may need to be delayed or the dose reduced if the blood tests show any problems with your liver.

## **Hand-foot (palmar plantar) syndrome**

When taking everolimus the palms of the hands and the soles of the feet can become red and sore. Sometimes you may also notice a tingling sensation, numbness or some swelling.

If you experience skin reactions, mention this to your specialist team so that the symptoms can be managed. Your doctor may prescribe a lotion, moisturiser or painkillers to help.

# **7. Rare side effects of everolimus**

## **Heart changes**

Rarely, everolimus may cause heart changes by weakening the heart muscle. This is usually temporary, but for a small number of people it may be permanent. Before you start treatment your specialist will arrange a heart (cardiac) function test to make sure your heart is working normally. This could be an electrocardiogram (ECG), which takes an electrical recording of your heart, or an echocardiogram (echo).

Contact your specialist team if you develop any breathlessness, chest pain, changes to your heartbeat or swollen ankles.

## **Slow wound healing**

Sometimes, everolimus may delay wound healing, so if you have to have an operation you may need to stop taking everolimus for a short time and start it again once your wound has healed. Your specialist team can tell you more about this.

## 8. Blood clots

People with breast cancer have a higher risk of blood clots. Their risk is higher because of the cancer itself and some treatments for breast cancer. If the cancer has spread to other parts of the body (secondary breast cancer), this also increases the risk.

Having everolimus increases the risk of blood clots such as deep vein thrombosis (DVT). People with a DVT are at risk of developing a pulmonary embolism. This is when part of the blood clot breaks away and travels to the lung.

Blood clots can be harmful but are treatable so it's important to report symptoms as soon as possible.

If you experience any of the following symptoms contact your local A&E department, GP or specialist team straight away:

- pain, redness/discolouration, heat and swelling of the calf, leg or thigh
- swelling
- shortness of breath
- tightness in the chest
- unexplained cough (may cough up blood)

## 9. Sex and contraception

You're advised not to become pregnant while you're having treatment because everolimus may have a harmful effect on a developing baby. If you haven't been through the menopause, talk to your team about the most suitable method of contraception for you. You should continue using contraception for at least seven months after your last dose of everolimus.

## 10. Travel and vaccinations

### Travel vaccinations

Vaccines may be less effective if given during treatment. You shouldn't have any live vaccines (vaccines containing active viruses) while having everolimus as they could be harmful and cause infections. Live vaccines include those that protect against measles, rubella, yellow fever and typhoid.

If you're planning a trip and need vaccinations, discuss this with your specialist team or practice nurse.

## Flu vaccination

Anyone with a reduced immunity to infection should have a flu vaccine. This includes people having or due to have everolimus. The flu vaccine is not a live vaccine.

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Next planned review begins 2020