

My Guide

for breast cancer
treatment with
AFINITOR®

Information
and advice

**AFINITOR**
(everolimus) tablets

WHAT IS AFINITOR?

AFINITOR is:

- A once-daily prescription medicine taken by mouth
- A targeted therapy, different from conventional hormonal therapy and chemotherapy
- Enhances hormonal therapy when hormonal therapy alone can no longer keep the disease under control
- Is taken together with exemestane, a type of medicine called a steroidal aromatase inhibitor, a hormonal therapy used in breast cancer

Types of Breast Cancer Drug Treatments



targeted therapy
(such as AFINITOR)



hormonal therapy
(such as exemestane)

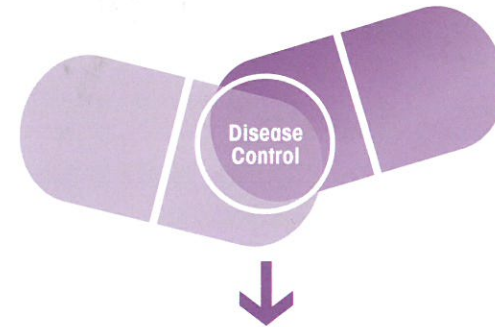


chemotherapy

WHY HAVE I BEEN PRESCRIBED AFINITOR?

You have been prescribed AFINITOR for the treatment of hormone receptor-positive (HR+), HER2- advanced breast cancer. Breast cancers can develop resistance to treatment and may require a change in medication to re-establish control of the disease. AFINITOR, together with exemestane may decrease the chance of the cancer growing.

AFINITOR + exemestane



2x

AFINITOR in combination with exemestane has shown to **DOUBLE THE TIME BEFORE PROGRESSION OCCURS** compared with exemestane alone.

HOW TO TAKE AFINITOR?



The usual dose of AFINITOR is 10 mg, once a day. Take this with one 25 mg exemestane tablet.



AFINITOR is also available as 5 mg

Tablets shown not actual size

AFINITOR should be taken:

- As prescribed by your doctor
- Consistently, either on an empty stomach or after a light fat-free meal

AFINITOR should not be taken

- With a high fat meal, as it can interfere with the absorption of AFINITOR and make it less effective
- With grapefruit, grapefruit juice, star fruit, Seville oranges (including marmalade) and St. John's wort
- There are certain medications that should not be taken together with AFINITOR, refer to Page 16 or talk to your doctor if you have any concerns about taking AFINITOR with your existing medicines

Refer to
My Diary for
a list of things
to remember
when taking
AFINITOR



HOW TO STORE AFINITOR

- Store AFINITOR at room temperature (below 30°C) in the original package to protect it from light and moisture
- Do not use AFINITOR after the expiry date printed on the carton and blister foil or if the pack shows signs of tampering



WHAT TO DO IF YOU MISS A DOSE

If you forget to take a tablet, and:

- It is less than 6 hours after you would normally take it, you should still take the tablet. Then go back to taking your medicine as you would normally
- It is more than 6 hours after you would normally take it, skip the tablet you missed and take your next tablet as scheduled

- Do not take a double dose to make up for a forgotten tablet

WHAT TO EXPECT FROM TAKING AFINITOR

Medicines can cause unwanted side effects

AFINITOR may cause side effects and you should be aware that some people experience side effects as quickly as hours after beginning treatment. You are unique and will react to AFINITOR treatment in a different way than others.

Remember, it is vital you take AFINITOR as directed by your doctor. This may help prevent or minimise the side effects you experience.


What are the common side effects of AFINITOR?

The following pages cover some common side effects, how you can identify them and what you could do. You may experience some of these side effects, but it is unlikely you will experience all of them.

Side effects can be managed

To manage side effects, your doctor may adjust the dose of AFINITOR, interrupt dosing intermittently or cease the medication if required.

You should have also been given a diary. Note any side effect you may experience using the Symptom Tracker to ensure you talk to your doctor or nurse at your next medical appointment.



Don't forget to talk to your doctor or nurse as soon as you experience any side effect so it can be managed. The sooner you can identify a side effect, the sooner it can be managed.

Please review the Consumer Medicine Information for a complete list of AFINITOR side effects.



Mouth ulcers



What to look out for and when:

- AFINITOR-related mouth ulcers are common and tend to occur soon after starting AFINITOR, usually within the first 6 weeks and often within the first 2 weeks
 - If you do not experience mouth ulcers within the first 6–8 weeks of treatment, there is a good chance that you will not experience this side effect
- Mouth ulcers are characterised by
 - Sores/redness on your mouth, lips, gums or throat
 - Sensations of tenderness, swelling, tingling, pain or burning
 - Changes in, or difficulty eating, drinking or swallowing
 - Changes in taste

Tips:

- Avoid food and drinks that can irritate your mouth such as citrus fruits and juices that are acidic, spicy, salty, hard or crunchy foods
- Avoid very hot foods; let food cool down before you eat
- Take good care of your mouth and visit your dentist regularly
 - Use a soft-bristled toothbrush and mild toothpaste
If you normally floss, continue to do so
 - Rinse your mouth frequently with bland rinses, such as water, salty water or sodium bicarbonate
 - Avoid mouthwash containing alcohol, hydrogen peroxide, iodine, or thyme derivatives because it may irritate your mouth

Your doctor or nurse can advise you what to do when you begin to experience any of the symptoms



Nausea

What to look out for and when:

- You may experience nausea and/or vomiting whilst taking AFINITOR. Onset of symptoms may occur within a few hours after beginning AFINITOR treatment

Tips:

- If you feel sick and vomit, tell your doctor or nurse
- If you continue to vomit or feel light-headed and/or you have a fever, inform your doctor or nurse without delay



Diarrhoea

What to look out for and when:

- Diarrhoea may happen at any time during treatment
- Monitor any new or worsening symptoms of diarrhoea including
 - Frequent watery stools
 - Dehydration (excessive thirst and/or dry mouth, weakness, dizziness)
 - Abdominal pain
 - Fever
 - Blood in stool

Tips:

- Dehydration is a consequence of diarrhoea, ensure that you drink more liquids
 - Avoid alcohol and drinks containing caffeine
 - Consider using a rehydration supplement such as Hydralyte®
- Lactose-containing foods, such as dairy products, may worsen diarrhoea and should be avoided
- Eat frequent small meals
- Consider taking loperamide (such as GastroStop®)
Speak to your pharmacist for advice
- Record episodes in your diary so you can report what happened to your doctor or nurse at the next appointment
- If your diarrhoea is not controlled and you have more than 5 loose bowel motions per day, and especially if you feel light-headed, dizzy or feverish, you should inform your doctor or nurse without delay



Rash



What to look out for and when:

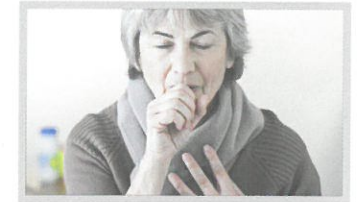
- Rash often appears within the first months of therapy
- Primarily occurs on the torso, scalp, face, and neck. Arms and legs are also commonly involved

Tips:

- Use unscented moisturising cleanser with lukewarm water when bathing/showering
- Apply sunscreen (SPF 30 or higher) when going outdoors
- Moisturise frequently, with a gentle, alcohol-free moisturiser, such as one suitable for babies
- Monitor and report any new or worsening skin rash to your doctor or nurse



Coughing or shortness of breath



What to look out for and when:

- General respiratory symptoms such as coughing or shortness of breath can be an early sign of a more serious side effect called pneumonitis
 - Pneumonitis can occur anytime during treatment with AFINITOR but usually it does not occur early on – studies have shown that only approximately one quarter (25%) of cases occur within the first 3 months of treatment
- Early symptoms can include any new or worsening of breathing problems, such as a dry cough or shortness of breath
 - As an example, this may include feeling out of breath during normal daily activities, such as walking to the shops, where this activity did not make you short of breath before

Tips:

- Promptly report any new or worsening respiratory symptoms, such as cough, shortness of breath, difficulty breathing, hypoxia (dizziness and/or tiredness on exertion) to your doctor or nurse
- If you become short of breath or develop chest pain, immediately go to Emergency at the nearest hospital or call an ambulance



Hyperglycaemia

Hyperglycaemia is the term used to describe higher than normal sugar levels in the blood.

What to look out for and when:

- Approximately half of all hyperglycaemia events occur within the first 6 weeks of treatment with AFINITOR
- Hyperglycaemia can cause symptoms such as
 - Feeling thirsty
 - Having to empty your bladder more often
 - Weight loss
 - Blurred vision
 - Being more tired than usual or have difficulty concentrating

Tips:

- Proactively implement lifestyle changes
 - Drink plenty of water
 - Exercise regularly
 - Reduce dietary amounts of carbohydrates and sugars

Your doctor will monitor your blood sugar levels on an ongoing basis via blood tests. If you develop symptoms or feel unwell, inform your doctor or nurse



Fever and infections

What to look out for and when:

- AFINITOR may affect your immune system increasing the risk of infection during treatment
- Pay attention to early signs of an infection, which include
 - Fever
 - Chills
 - Coughing
 - Sore throat
 - Loss of appetite
 - Nausea
 - Joint pain
 - Tiredness

Tips:

- Although it is impossible to completely protect against infection, having good daily hygiene practices (e.g. hand washing thoroughly and often) may help minimise your exposure to common germs
- Drink plenty of fluids, especially water

Your blood count will be checked by your doctor at different times before and during your treatments. If you develop a fever of 38°C or higher or have shivers, shakes or feel unwell, immediately go to Emergency at the nearest hospital.





Fatigue

What to look out for and when:

- Fatigue is a common issue for people undergoing cancer treatment and can be worsened by additional treatment
- Fatigue generally occurs within the first 6 weeks of treatment with AFINITOR

Tips:

- Limit your daily activities and concentrate on what is most important to you
- Although counter intuitive and difficult to start, regular exercise along with plenty of rest, has been shown to help improve fatigue

WHAT SHOULD I DO IF I EXPERIENCE A SIDE EFFECT?

Tell your doctor or nurse about any side effects you have while taking AFINITOR as soon as possible. Symptoms may worsen if not dealt with promptly. Your doctor or nurse has many ways to help manage your side effects so that you can stay on treatment for as long as possible.

Your doctor may add another prescription medicine or recommend an over the counter medicine or other product to ease certain symptoms. It is important to inform your doctor or nurse as soon as possible about any possible side effects so that they can act promptly. They may interrupt your AFINITOR dose for a short period of time until your side effect(s) gets better or reduce your AFINITOR dose, or both.

Do not stop taking AFINITOR unless you have been advised to do so.

The sooner a side effect is recognised, the sooner it can be treated

Dosing changes are part of your AFINITOR treatment

IMPORTANT INFORMATION

Immediately go to Emergency at the nearest hospital if you:

- suddenly become unwell
- experience difficulty eating or drinking
- feel short of breath or experience rapid breathing
- develop chills, shivers or shakes
- develop a temperature of 38°C or above
- develop chest pain
- notice pain or swelling in your legs or arms



SIMULTANEOUS THERAPY/ DRUG INTERACTIONS

Some medicines may interfere with AFINITOR and may require different amounts of or an alternative medicine. Inform your doctor if you are currently taking any other medications (including prescription medicines, over the counter medicines, herbal and vitamin supplements). Here are some drugs that we know may interact with AFINITOR, but is not a complete list.

- antibiotics such as rifampicin, rifabutin, clarithromycin and erythromycin
- antifungal medicines such as voriconazole, fluconazole and itraconazole
- medicines for high blood pressure or heart problems such as diltiazem and verapamil
- drugs used to treat HIV/AIDS such as ritonavir, amprenavir, fosamprenavir, efavirenz and nevirapine
- epilepsy medicines such as carbamazepine, phenobarbitone and phenytoin
- St John's wort
- drugs used to stop the body from rejecting organ transplants such as cyclosporin
- drugs used to prevent vomiting such as aprepitant
- midazolam, a medicine used to treat acute seizures, or used as a sedative before or during surgery or a medical procedure

Some medicines may interfere with AFINITOR and you may require different amounts of your medicines, or an alternative medicine.

VACCINATIONS

The use of vaccinations together with AFINITOR may alter the effectiveness of either treatment. In particular, the use of live vaccines should be avoided during treatment with AFINITOR. Examples of live vaccines include: intranasal influenza, measles, mumps, rubella, oral polio, BCG, yellow fever, varicella, and Ty21a typhoid vaccines.

Talk to your doctor or nurse before you decide on vaccination

Further information:

This guide is intended for patients who have been prescribed AFINITOR for advanced breast cancer.

For Consumer Medicine Information (CMI), go to http://www.novartis.com.au/products_consumers.html or ask your pharmacist for a copy.

Additional resources:

- **Breast Cancer Network Australia** by visiting www.bcna.org.au
- **eviQ Cancer Treatments Online**, ask your doctor or nurse for the AFINITOR information sheet, or register as a consumer on their website: www.eviq.org.au

The information in this booklet should not replace the advice of your doctor.

Talk to your doctor if you have any questions about your treatment. He/she is the best person to answer any questions you may have about AFINITOR or any other aspect of your treatment.



