AFINITOR®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Afinitor?

Afinitor contains the active ingredient everolimus. Afinitor is used to treat various types of cancer by slowing the growth of cancer-causing cells.

For more information, see Section 1. Why am I using Afinitor? in the full CMI.

2. What should I know before I use Afinitor?

Do not use if you have ever had an allergic reaction to Afinitor or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use Afinitor? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Afinitor and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Afinitor?

- Your doctor will tell you the dose of Afinitor that you should take.

More instructions can be found in Section 4. How do I use Afinitor? in the full CMI.

5. What should I know while using Afinitor?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using Afinitor. • Avoid becoming pregnant while using Afinitor and for up to 8 weeks after you stop using it.
Things you should not do	• Do not stop using this medicine suddenly. • Do not take Afinitor to treat any other complaints unless your doctor tells you to. • Do not give your medicine to anyone else, even if they have the same condition as you.
Driving or using machines	• It is not known if Afinitor will influence your ability to drive and use machines.
Drinking alcohol	• There are no known interactions between Afinitor and alcohol.
Looking after your medicine	• Store below 30°C in the original packaging. Store it in a cool dry place away from moisture, heat or sunlight. • Keep out of reach of children.

For more information, see Section 5. What should I know while using Afinitor? in the full CMI.

6. Are there any side effects?

Common side effects include infections, rash, feeling weak or tired, diarrhoea, swelling of arms, hands, feet, ankles, face or other parts of the body, abdominal pain, nausea, fever, cough, headache, decreased appetite. For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

AFINITOR®

Active ingredient(s): *everolimus*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Afinitor. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Afinitor.**

Where to find information in this leaflet:

1. Why am I using Afinitor?
2. What should I know before I use Afinitor?
3. What if I am taking other medicines?
4. How do I use Afinitor?
5. What should I know while using Afinitor?
6. Are there any side effects?
7. Product details

1. Why am I using Afinitor?

Afinitor contains the active ingredient everolimus. Afinitor is classed as an inhibitor targeting mTOR (mammalian target of rapamycin). Afinitor is used to treat various types of cancer by slowing the growth of cancer-causing cells.

Afinitor is used in the treatment of:

- **Renal cell carcinoma, a type of kidney cancer**

Afinitor stops the cancer from making new cells and cuts off the blood supply. This slows the growth and spread of the cancer.

- **Neuroendocrine tumours (NETs)**

Afinitor is used to control the growth of these tumours located in the stomach and intestine, lung or pancreas.

- **Tuberous sclerosis complex (TSC) with angiomyolipoma of the kidney not requiring immediate surgery**

Afinitor may reduce the size of the tumour that is associated with a genetic disorder called TSC. This may lower the risk of the tumour(s) causing bleeding complications and may help to preserve kidney function.

- **TSC with subependymal giant cell astrocytoma (sometimes called 'SEGA'), not requiring immediate surgery**

Afinitor reduces the size of brain tumours (SEGA) that are caused by a genetic disorder called tuberous sclerosis. This may stop the tumours from causing problems as they grow, such as hydrocephalus (excessive accumulation of fluid within the brain).

- **TSC with seizures in patients 2 years and older**

Afinitor may reduce the frequency of seizures in patients with a genetic disorder called TSC.

- **Hormone receptor-positive, HER2 negative advanced breast cancer in postmenopausal women**

Growth of this type of breast cancer is stimulated by oestrogens which are female sex hormones. Oestrogen inhibitors such as letrozole, anastrozole and exemestane reduce the amount of oestrogen and can slow the growth of breast cancers. After failure of letrozole or anastrozole, exemestane is used in combination with Afinitor to prevent the breast cancer cells from becoming resistant to the exemestane. **It is only used in patients whose tumour has tested negative to HER2.**

2. What should I know before I use Afinitor?

Warnings

Do not use Afinitor if:

- you are allergic to everolimus, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine
- you have an allergy to everolimus-related medicines such as Rapamune, which contains the active ingredient sirolimus.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Check with your doctor if you:

- have or have had problems with your liver; It may be necessary to modify your dose of Afinitor
- have or have had diabetes or high levels of blood sugar
- have previously had Hepatitis B
- have received or about to receive radiation treatment
- have lactose intolerance
- have allergies to any other medicines, foods, preservatives or dyes
- have had or about to have recent surgery, or have an unhealed wound following surgery
- have any type of infection; it is important to treat your infection before starting Afinitor
- are scheduled to receive any vaccine
- have any other medical conditions
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Afinitor is not recommended for use during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Breastfeeding is not recommended while you are taking Afinitor and for two weeks after the last dose of Afinitor. It is not known whether Afinitor passes into breast milk and could affect your baby.

Contraception

To avoid becoming pregnant, you should use effective contraception while using Afinitor and for up to 8 weeks after you stop using it.

Children and adolescents

Afinitor can be used in children or adolescents with normal liver function for the treatment of:

- TSC with SEGA (starting at 1 year of age)
- TSC with seizures SEGA (starting at 2 years of age).

Afinitor is not to be used in children or adolescents for the treatment of cancer, or TSC with angiomyolipoma of the kidney.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Afinitor and affect how it works.

- Antibiotics such as rifampicin, rifabutin, clarithromycin and erythromycin
- Antifungal medicines such as ketoconazole, voriconazole, fluconazole and itraconazole
- Medicines for high blood pressure or heart problems such as diltiazem and verapamil
- Medicines used to treat high blood pressure or other heart problems, known as ACE inhibitors
- Medicines used to treat HIV/AIDS such as ritonavir, amprenavir, fosamprenavir, efavirenz and nevirapine
- Medicines for epilepsy such as carbamazepine, phenobarbitone and phenytoin. If you are taking a medicine to control seizures, any change in the dose of your medication may require a change in your Afinitor dose
- Cannabidiol used to treat epilepsy and chronic pain, and to improve symptoms related to muscle stiffness and spasms in multiple sclerosis
- St John's wort, a herbal product used to treat depression and other conditions
- Drugs used to stop the body from rejecting organ transplants such as ciclosporin
- Medicines 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Afinitor.

Vaccines - tell your doctor if you need to get a vaccination. Some vaccines may be less effective if given while taking Afinitor.

4. How do I use Afinitor?

Afinitor is available as tablets and dispersible tablets. The tablets can be used for the various cancers, TSC with SEGA, and TSC with kidney angiomyolipoma. It is not recommended for use in TSC with seizures. The dispersible tablets can be used for TSC with SEGA and TSC with seizures.

How much to take

Your doctor will tell you how many Afinitor tablets or dispersible tablets to take. The dose will depend on the condition you are being treated for and your individual treatment needs.

When to take Afinitor

- Take Afinitor once a day, at the same time each day
- It is best to take Afinitor in the morning, either consistently with or without food
- Do not drink grapefruit juice or eat grapefruit, star fruit or Seville oranges while taking Afinitor. These foods can stop Afinitor from working properly.

How to take Afinitor

<u>Afinitor Tablets</u>

Swallow the tablets whole with a glass of water. Do not chew or crush the tablets.

If you cannot swallow Afinitor tablets whole, you can stir the tablet into a glass of water:

- Put the required number of tablets into a glass containing approximately 30 mL of water
- Gently stir until the tablets break apart (approximately 7 minutes) then drink immediately
- Rinse the glass with the same amount of water (approximately 30 mL) and drink the contents to make sure that you get the full dose of Afinitor.

<u>Afinitor Dispersible Tablets</u>

Afinitor Dispersible Tablets must be made into a suspension in water first. Do not use any other liquid. Do not chew, crush, or swallow the Dispersible Tablets whole.

You can prepare the suspension in an oral syringe or in a small drinking glass. The suspension must be taken right away. If you do not take the dose within 60 minutes after it has been prepared, throw away the dose and prepare a new dose of Afinitor Dispersible Tablets.

<u>Oral Syringe</u>

- Remove the plunger from a 10 mL oral syringe and put the prescribed number of dispersible tablets inside the syringe
- Re-insert the plunger and push it inward to make contact with the dispersible tablets
- Pull up about 5 mL of water into the syringe to cover the dispersible tablets. Then pull in about 4 mL of air.

- Place the filled syringe into a container (tip up) for 3 minutes and allow the tablets to disintegrate
- Gently turn the oral syringe upside down 5 times immediately prior to taking the medicine
- Carefully push the plunger to remove the excess air from the syringe and then immediately dispense the full contents of the oral syringe directly into the mouth of the patient so they can drink the medicine
- After taking the medicine, pull up about 5 mL of water and 4 mL of air into the same syringe and swirl the contents and then put the entire contents of the syringe into the mouth of the patient.

Small drinking glass

- Add approximately 25 mL (2 tablespoons) of water into a small drinking glass and add the prescribed number of dispersible tablets. Do not add more than 10 mg of Afinitor dispersible tablets to the glass. If you need to take more than 10 mg, prepare another glass
- Allow the dispersible tablets to disintegrate for 3 minutes
- Stir the contents of the glass gently with a spoon and immediately drink the full amount
- Refill the glass with the same amount of water (about 25 mL), stir the contents with the same spoon to suspend remaining particles, and drink the entire content of the glass.

Instructions for use and handling of tablets and dispersible tablets

Caregivers are advised to avoid contact with suspensions of Afinitor tablets or dispersible tablets. Wash hands thoroughly before and after preparing either suspension.

If you forget to use Afinitor

Afinitor should be taken regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember, and then take the next tablet as usual.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you use too much Afinitor

If you think that you have taken too much Afinitor, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Afinitor?

Things you should do

- Keep all of your doctor's appointments so that your progress can be checked
- Tell your doctor if you plan to receive a vaccine
- Avoid becoming pregnant while using Afinitor and for up to 8 weeks after you stop using it
- Tell your doctor if you are about to have surgery, have had recent surgery or if you still have an unhealed wound following surgery.

Call your doctor straight away if you:

- Experience new or worsening cough, difficulty breathing, chest pain, shortness of breath or wheezing
- Have a temperature or chills, or another sign of an infection
- Experience pain or discomfort in the mouth or have open sores in the mouth
- Experience shortness of breath, nausea, diarrhoea, skin rashes or soreness in the mouth, gums or throat
- Become pregnant while taking this medicine.

Remind any doctor, dentist or pharmacist you visit that you are using Afinitor.

Things you should not do

- Do not stop using this medicine suddenly
- Do not change your dose, or switch between tablets and dispersible tablets unless advised by your doctor
- Do not take Afinitor to treat any other complaints unless your doctor tells you to
- Do not give your medicine to anyone else, even if they have the same condition as you.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Afinitor affects you.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Keep the tablets or dispersible tablets in the original packet and foils until it is time to take them.

Store below 30°C in the original packaging.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Mouth, stomach, bowel problems: • Sore mouth or throat, cold sores or mouth ulcers • Nausea, vomiting, diarrhoea, constipation, tummy pain, excess gas • Dry mouth, difficulty swallowing • Loss of appetite, change in or loss of taste, weight loss • Cloudy urine, pain when urinating, wanting to urinate more often **General problems:** • Feeling thirsty • Fatigue or unusual weakness • Trouble sleeping • Headache, dizziness • Ear ache • Runny nose, cough • Fever • Nose bleeds • Irregular, absent or heavy menstrual periods in females • Joint pain • Poor wound healing • Swelling of hands, feet or limbs due to fluid retention **Skin problems:** • Bleeding or bruising more easily than normal • Small, solid pink or red bumps on the skin • Dry or red skin, rash • Nail disorders • Rash and pain on the palms of your hands or soles of your feet • Pimples	**Speak to your doctor if you have any of these less serious side effects and they worry you.** **If these side effects become severe, tell your doctor, pharmacist or healthcare provider**

Serious side effects

Serious side effects	What to do
Symptoms of an allergic reaction or infection such as: • Shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin • Fever, chills, sore throat, aching joints and inflammation, swollen glands, cough, or any other signs of infection such as infection of a cut or scratch • Painful skin rash with small fluid-filled blisters in a limited area on one side of the body (left or right), often in a stripe (herpes zoster) **Lung or heart problems such as:** • Coughing, breathing problems, rapid breath or shortness of breath • Sudden onset of shortness of breath, chest pain or coughing up blood **Other problems:** • Difficulty breathing, nausea, diarrhoea, soreness in the mouth, gums or throat, skin rashes or redness at site of radiation therapy • Symptoms of hepatitis B such as fever, skin rash, joint pain, inflammation, fatigue, loss of appetite, nausea, jaundice (yellowing of the skin), pain in the upper right abdomen, pale stool or dark urine • Swelling and/or pain in one of your legs, usually your calf, (redness or warm skin in the affected area) • Swelling, feeling of heaviness or tightness, pain, limited movement of body parts which could be a sign of fluid build-up and a problem with your lymphatic system • Vomiting blood, blood in your faeces • Signs of anger, easily irritated	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people. Some of these side effects can only be found by laboratory testing (for example, high levels of cholesterol, lipids, or sugar in the blood).

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at

www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Afinitor contains

Active ingredient (main ingredient)	everolimus
Other ingredients (inactive ingredients)	Afinitor Tablets • butylated hydroxytoluene • magnesium stearate • lactose monohydrate • hypromellose • crospovidone • lactose Afinitor Dispersible Tablets • butylated hydroxytoluene • magnesium stearate • lactose monohydrate • hypromellose • crospovidone • mannitol • microcrystalline cellulose • colloidal anhydrous silica
Potential allergens	Lactose

Do not take this medicine if you are allergic to any of these ingredients.

What Afinitor looks like

Afinitor Tablets

Afinitor tablets are available in three different strengths, supplied in packs of 30 tablets:

- Afinitor 2.5 mg tablets are white to yellowish and elongated with no score, with "LCL" on one side and "NVR" on the other (AUST R 177648)
- Afinitor 5 mg tablets are white to yellowish and elongated with no score, with "5" on one side and "NVR" on the other (AUST R 154661)
- Afinitor 10 mg tablets are white to yellowish and elongated with no score, with "UHE" on one side and "NVR" on the other (AUST R 154663)

Afinitor Dispersible Tablets

Afinitor dispersible tablets are available in three different strengths, supplied in packs of 30 tablets:

- Afinitor 2 mg dispersible tablets are white to slightly yellowish, round, flat tablets with a bevelled edge and no score, with "D2" on one side and "NVR" on the other (AUST R 200203)
- Afinitor 3 mg dispersible tablets are white to slightly yellowish, round, flat tablets with a bevelled edge and no score, with "D3" on one side and "NVR" on the other (AUST R 200204)
- Afinitor 5 mg dispersible tablets are white to slightly yellowish, round, flat tablets with a bevelled edge and no score, with "D5" on one side and "NVR" on the other (AUST R 200205)

Who distributes Afinitor

Afinitor is supplied in Australia by:

Novartis Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

Level 25, Victoria Cross Tower

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Telephone 1 800 671 203

Website: www.novartis.com.au

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