Everolimus AFINITOR® and generics

Patient information sheet V3, June 2024



WHAT IS AFINITOR® EVEROLIMUS?

- A targeted therapy used to treat some breast and kidney cancers and for some neuroendocrine tumours
- Prescribed and renewed by your hospital-based oncologist, haematologist or cancer specialist
- Available from community pharmacies on presentation of your prescription



- Oval tablet, white to slightly yellowish, dosed at:
- 2.5 mg, with "LCL" on one side and "NVR" on the other
- 5 mg, with "5" on one side and "NVR" on the other
- 10 mg, with "UHE" on one side and "NVR" on the other
- Generic medicines may have a different form or colour



- Do not store above 25°C, and keep out of the sight and reach of children
- Do not take the tablets out of the box to put them in a pillbox
- Wash your hands carefully before and after handling the tablets
- · Do not throw away opened packs, please return them to your pharmacist

HOW TO TAKE THIS MEDICINE

When? = 1 dose per day at a set time, with or without a meal

Swallow the tablet(s) whole, with water, one after another, at the same time every day.

Do not chew, cut, crush or dissolve them.

You can use your **medical diary*** and a **calendar** to note doses.

Do not stop taking or change how you take your treatment without consulting your doctor.

This leaflet is not a prescription, please refer to your most recent prescription.

IF YOU FORGET TO TAKE YOUR MEDICINE OR VOMIT



- If you forget to take your medicine, do not take the missed dose. Take your next dose at the usual time, do not take a double dose. Keep a record in your medical diary*.
- If you throw up, do not take another dose. Take your next dose at the usual time, do not take a double dose. Keep a record in your medical diary*.

INTERACTION WITH OTHER MEDICINES AND OTHER INTERACTIONS



Check with **your doctor or pharmacist** that the medicines (prescribed or over-the-counter), other substances (foods, spices and plants, including **grapefruit** and **St. John's Wort**, probiotics, essential oils, food supplements, etc.) and derivative products you use are **compatible with your treatment**. The molecules they contain, their dose and how often they are taken can interact with your treatment and affect its effectiveness and the occurrence of side effects.



- You and your partner must use effective methods of contraception (condoms and another method) throughout treatment and for 8 weeks after the last dose.
- Stop breastfeeding during treatment and for 2 weeks after the last dose.

Male and female fertility can be affected during treatment with everolimus. Your doctor can tell you more about the possibility of sperm banking before starting treatment.

*Patient diary available (in French) at <u>www.omedit-fiches-cancer.fr</u>

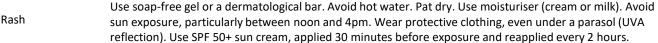


WHAT SIDE EFFECTS CAN OCCUR WITH AFINITOR® EVEROLIMUS?

Like all medicines, everolimus may cause side effects, although not everybody gets them.

Side effects

Prevention



Elevated cholesterol levels

Limit saturated fatty acids (e.g. cheese, cream, butter, fatty meat, cold meats). Eat more white fish, grains, carbohydrates, dairy products, fruit and vegetables. Steam, bake, boil or grill food. Exercise regularly.



Digestive effects: nausea, vomiting, loss of appetite, diarrhoea

Monitor your weight and remember to hydrate (1.5 to 2 L water per day). In case of diarrhoea, eat foods low in fibre (carbohydrates, carrots, bananas etc.). Avoid foods that can stimulate digestion (dairy products, raw fruit/vegetables, grains, fatty foods, spices). In case of nausea/vomiting, divide your meals into several small meals and eat slowly. Avoid fatty, fried or spicy foods, and foods that smell strongly. Avoid having an empty stomach (can worsen nausea). Drink between, rather than with, meals. Use your prescribed antiemetics if applicable.



Inflamed mouth

Use a soft toothbrush and menthol-free, additive-free toothpaste. Keep your lips hydrated (ask your pharmacist for advice, particularly if you are receiving oxygen therapy. Stimulate saliva production (ice cubes, sorbets). Prefer liquids and blended foods. Avoid alcohol, tobacco, coffee and acidic, salty, irritating, spicy and crunchy foods. Use pain medication. Use your prescribed mouthwash (not mouthwash containing alcohol).



High blood pressure

Headaches, dizziness, and tinnitus are the first warning signs of high blood pressure. Measure your blood pressure (resting and sitting down, in the morning before breakfast and in the evening before going to bed; take three measurements two minutes apart); keep a record of your results. Exercise regularly (suitable activities) (30 minutes 3 times per week). Limit salt (max. 5 g per day) and alcohol. Eat a diet low in saturated fats (animal fats) and high in fibre.

Nosebleeds: Tilt your head forward until bleeding stops and gently blow your nose to clear clots. Pinch your



unusual bleeding,

Nosebleeds,

bruising

nostrils for 10 minutes; haemostatic products can reduce this time (packing applied after 2 minutes of compression and left in place for 30 minutes). If bleeding continues for more than 15 minutes of compression or in case of paleness, palpitations, sweating or low blood pressure: consult a doctor immediately. Use a soft toothbrush. Do not use rectal thermometers. Do not take aspirin, anti-inflammatories (e.g. Ibuprofen), or herbal products (that can increase bleeding) without medical guidance: consult a healthcare professional. In case of bruising, apply cold (compress or ice pack) or a suitable cream/gel (e.g. arnica) if the skin is not broken.



Risk of infection

Limit contact with people with infections. Wash your hands regularly. Disinfect all wounds thoroughly. Contact your doctor in case of temperature > 38°C, cough, shortness of breath/pain on breathing, pain when urinating/smelly urine, change in type/frequency of bowel movements (diarrhoea, constipation), or in case of redness, pain or discharge around your central line, feeding tube or urinary catheter.



Tiredness, headache, insomnia

Drink sufficient quantities (1.5 to 2 L water per day) and eat healthily, at regular intervals. Avoid using psychostimulants (e.g. coffee, tobacco, alcohol). Rest during the day, while maintaining up to moderate levels of activity. Establish a sleep schedule; avoid going to bed and getting up late. Take care when driving.



Only the most common side effects are listed here. For more information, read the Patient Leaflet included with your medicine or ask your doctor or pharmacist.

You can also ask your Regional Pharmacovigilance Centre and report any side effects online: signalement-sante-gouv-fr



Remember to go for the lab tests prescribed by your doctor.

What to do if you experience side effects

Contact your doctor rapidly in case of:

- Signs of infection (fever, cough, chills, etc.)
- Bleeding, black faeces, coughing up blood
- Shortness of breath, lightheadedness, dizziness, chest pain
- Pain, redness or swelling of the legs
- Any persistent or worsening side effect

Useful cont	acts:

Note: