Mobocertinib (Exkivity™)

Pronounced: moe-boe-SER-ti-nib

Classification: Kinase Inhibitor

About Mobocertinib (Exkivity™)

Mobocertinib is a kinase inhibitor. A kinase is an enzyme that promotes cell growth. There are many types of kinases, which control different phases of cell growth. By blocking a particular enzyme from working, this medication can slow the growth of cancer cells. This medication works against the epidermal growth factor receptor (EGFR) exon 20 insert mutation that is found on some cancer cells. Your tumor will be checked for this mutation.

How to Take Mobocertinib

Mobocertinib is taken as a capsule by mouth, with or without food, around the same time each day. Swallow the capsule whole. Do not crush, chew, or open the capsules. If a dose is missed by more than 6 hours, skip the dose and take the next dose the following day at your normal time. If you vomit after taking your dose do not take an extra dose. Instead, take your next dose as scheduled.

It is important to make sure you are taking the correct amount of medication every time. Before every dose, check that what you are taking matches what you have been prescribed.

The blood levels of this medication can be affected by certain foods and medications, so they should be avoided. These include (but are not limited to): St. John’s wort, grapefruit, grapefruit juice, itraconazole, ketoconazole, diltiazem, fluconazole, verapamil, rifampin, bosentan, and efavirenz.

Storage and Handling

Store your medication in the original, labeled container at room temperature and in a dry location (unless otherwise directed by your healthcare provider or pharmacist). This medication should not be stored in a pillbox. Keep containers out of reach of children and pets.

If a caregiver prepares your dose for you, they should consider wearing gloves or pouring the pills directly from their container into the cap, a small cup, or directly into your hand. They should avoid touching the pills. They should always wash their hands before and after giving you the medication. Pregnant or nursing women should not prepare the dose for you. Ask your oncology team where to return any unused medication for disposal. Do not flush down the toilet or throw in the trash.

Where do I get this medication?

Mobocertinib is available through select specialty pharmacies. Your oncology team will work with your prescription drug plan to identify an in-network specialty pharmacy for distribution of this medication and shipment directly to your home.

Insurance Information

This medication may be covered under your prescription drug plan. Patient assistance may be available to qualifying individuals depending upon prescription drug coverage. Co-pay cards, which reduce the patient co-pay responsibility for eligible commercially (non-government sponsored) insured patients, may also be available. Your care team can help you find these resources, if they are available.
Possible Side Effects of Mobocertinib

There are a number of things you can do to manage the side effects of mobocertinib. Talk to your care team about these recommendations. They can help you decide what will work best for you. These are some of the most common or important side effects:

**Heart Problems**

This medication can cause slow or abnormal heartbeats or an abnormal heart rhythm called QT prolongation. Your heart function will be checked prior to you starting this medication. Your electrolyte levels, including potassium and magnesium, will also be monitored using blood tests as these can affect heart function. Notify your oncology care team right away if you feel abnormal heartbeats or if you feel dizzy or faint.

This medication can also cause or worsen pre-existing heart problems including congestive heart failure, restrictive cardiomyopathy, decreased heart function, and heart attack. Notify your healthcare provider if you have sudden weight gain or swelling in the ankles or legs. If you develop chest pain or pressure, pain in the left arm, back, or jaw, sweating, shortness of breath, clammy skin, nausea, dizziness, or lightheadedness, call 911 or go to the nearest emergency room.

**Diarrhea**

Diarrhea can be a serious side effect of this medication. Notify your care provider if you start to have diarrhea to determine which medications you should be taking. Diarrhea can lead to dehydration so it is important to manage this side effect.

Your oncology care team can recommend medications to relieve diarrhea. Also, try eating low-fiber, bland foods, such as white rice and boiled or baked chicken. Avoid raw fruits, vegetables, whole-grain breads, cereals, and seeds. Soluble fiber is found in some foods and absorbs fluid, which can help relieve diarrhea. Foods high in soluble fiber include: applesauce, bananas (ripe), canned fruit, orange sections, boiled potatoes, white rice, products made with white flour, oatmeal, cream of rice, cream of wheat, and farina. Drink 8-10 glasses of non-alcoholic, un-cafeinated fluid a day to prevent dehydration.

**Skin and Nail Changes**

Some patients may develop a rash, scaly skin, or red itchy bumps. Use an alcohol-free moisturizer on your skin and lips; avoid moisturizers with perfumes or scents. Your oncology care team can recommend a topical medication if itching is bothersome. If your skin does crack or bleed, be sure to keep the area clean to avoid infection. Be sure to notify your oncology care team of any rash that develops, as this can be a reaction. They can give you more tips on caring for your skin.

While receiving this medication, you may develop an inflammation of the skin around the nail bed/cuticle areas of toes or fingers, which is called paronychia. It can appear red, swollen, or pus-filled. Nails may develop "ridges" in them or fall off. You may also develop cuts or cracks that look like small paper cuts in the skin on your toes, fingers, or knuckles. These side effects may appear several months after starting treatment but can last for many months after treatment stops.

- Follow the same recommendations for your skin (above).
- Don’t bite your nails or cuticles or cut the cuticles.
- Keep your fingernails and toenails clean and dry.
- You may use nail polish, but do not wear fake nails (gels, acrylics, overlay).
- Notify your healthcare provider if any nails fall off or you develop any of these side effects or other skin abnormalities.

**Low Red Blood Cell Count (Anemia)**

Your red blood cells are responsible for carrying oxygen to the tissues in your body. When the red cell count is low, you may feel tired or weak. You should let your oncology care team know if you experience any shortness of breath, difficulty breathing, or pain in your chest. If the count gets too low, you may receive a blood transfusion.

**Infection and Low White Blood Cell Count (Leukopenia or Neutropenia)**

White blood cells (WBC) are important for fighting infection. While receiving treatment, your WBC count can drop, putting you at a higher risk of getting an infection. You should let your doctor or nurse know right away if you have a fever (temperature greater than 100.4°F or 38°C), sore throat or cold, shortness of breath, cough, burning with urination, or a sore that doesn’t heal.
Tips to preventing infection:

- **Washing hands**, both yours and your visitors, is the best way to prevent the spread of infection.
- Avoid large crowds and people who are sick (i.e.: those who have a cold, fever or cough or live with someone with these symptoms).
- When working in your yard, wear protective clothing including long pants and gloves.
- Do not handle pet waste.
- Keep all cuts or scratches clean.
- Shower or bath daily and perform frequent **mouth care**.
- Do not cut cuticles or ingrown nails. You may wear nail polish, but not fake nails.
- Ask your oncology care team before scheduling dental appointments or procedures.
- Ask your oncology care team before you, or someone you live with has any vaccinations.

**Kidney Problems**

This medication can cause kidney problems, including an increased creatinine level, which your oncology care team may monitor for using blood tests. Notify your healthcare provider if you notice decreased urine output, blood in the urine, swelling in the ankles, or loss of appetite.

**Mouth Sores (Mucositis)**

Certain cancer treatments can cause **sores or soreness in your mouth** and/or throat. Notify your doctor or nurse if your mouth, tongue, inside of your cheek or throat becomes white, ulcerated or painful. Performing **regular mouth care** can help prevent or manage mouth sores. If mouth sores become painful, your doctor or nurse can recommend a pain reliever.

- Brush with a soft-bristle toothbrush or cotton swab twice a day.
- Avoid mouthwashes that contain alcohol. A baking soda and/or salt warm water mouth rinse (2 level teaspoons of baking soda or 1 level teaspoon salt in an eight ounce glass of warm water) is recommended 4 times daily.
- If your mouth becomes dry, eat moist foods, drink plenty of fluids (6-8 glasses), and suck on sugarless hard candy.
- Avoid smoking and chewing tobacco, drinking alcoholic beverages and citrus juices.

**Nausea and/or Vomiting**

Talk to your oncology care team so they can prescribe medications to help you manage **nausea and vomiting**. In addition, dietary changes may help. Avoid things that may worsen the symptoms, such as heavy or greasy/fatty, spicy or acidic foods (lemons, tomatoes, oranges). Try saltines, or ginger ale to lessen symptoms.

Call your oncology care team if you are unable to keep fluids down for more than 12 hours or if you feel lightheaded or dizzy at any time.

**Liver Toxicity**

This medication can cause liver toxicity, which your oncology care team may monitor for using blood tests called liver function tests. Notify your healthcare provider if you notice yellowing of the skin or eyes, your urine appears dark or brown, or you have pain in your abdomen, as these can be signs of liver toxicity.

**Decrease in Appetite**

**Nutrition** is an important part of your care. Cancer treatment can affect your appetite and, in some cases, the side effects of treatment can make eating difficult. Ask your oncology care team about nutritional counseling services at your treatment center to help with food choices.

- Try to eat five or six small meals or snacks throughout the day, instead of 3 larger meals.
- If you are not eating enough, nutritional supplements may help.
- You may experience a metallic taste or find that food has no taste at all. You may dislike foods or beverages that you liked before receiving cancer treatment. These symptoms can last for several months or longer after treatment ends.
- Avoid any food that you think smells or tastes bad. If red meat is a problem, eat chicken, turkey, eggs, dairy products and
fish without a strong smell. Sometimes cold food has less of an odor.

- Add extra flavor to meat or fish by marinating it in sweet juices, sweet and sour sauce or dressings. Use seasonings like basil, oregano or rosemary to add flavor. Bacon, ham and onion can add flavor to vegetables.

**Fatigue**

Fatigue is very common during cancer treatment and is an overwhelming feeling of exhaustion that is not usually relieved by rest. While on cancer treatment, and for a period after, you may need to adjust your schedule to manage fatigue. Plan times to rest during the day and conserve energy for more important activities. Exercise can help combat fatigue; a simple daily walk with a friend can help. Talk to your healthcare team for helpful tips on dealing with this side effect.

**Muscle or Joint Pain/Aches**

Your healthcare provider can recommend medications and other strategies to help relieve pain.

**Low Platelet Count (Thrombocytopenia)**

Platelets help your blood clot, so when the count is low you are at a higher risk of bleeding. Let your oncology care team know if you have any excess bruising or bleeding, including nose bleeds, bleeding gums, or blood in your urine or stool.

**Electrolyte Abnormalities**

This medication can affect the normal levels of electrolytes (potassium, magnesium, sodium, etc.) in your body. Your levels will be monitored using blood tests. If your levels become too low, your care team may prescribe specific electrolytes to be given by IV or taken by mouth. Do not take any supplements without first consulting with your care team.

**Less common, but important side effects can include:**

- **Pulmonary Toxicity:** This medication can affect the lungs. Patients can develop interstitial lung disease which is scarring of the lung tissue or pneumonitis which is an inflammation of the lungs. Notify your healthcare provider right away if you develop any new or worsening symptoms, including trouble breathing or shortness of breath, chest pain, cough, or fever.

**Reproductive Concerns**

Exposure of an unborn child to this medication could cause birth defects, so you should not become pregnant or father a child while on this medication. Effective non-hormonal birth control (condoms, diaphragm, copper IUD, cervical cap, and sponge) is necessary during treatment and for at least 1 month after treatment for women and 1 week after treatment for men. Even if your menstrual cycle stops or you believe you are not producing sperm, you could still be fertile and conceive. Do not breastfeed during treatment and for at least 1 week after the last dose.