Erdafitinib (Balversa™)

Pronounced: er-da-Fi-ti-nib

Classification: Tyrosine Kinase Inhibitor

About Erdafitinib (Balversa™)

Erdafitinib is a type of targeted therapy called a tyrosine 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.

Erdafitinib is a tyrosine kinase inhibitor that blocks an enzyme called a fibroblast growth factor receptor (FGFR). It works by targeting receptors present on the cancer cells. By blocking these targets on cancer cells, tumor growth and angiogenesis (the development of a blood supply to the tumor) are blocked, causing cell death. This medication specifically targets FGFR2 or FGFR3 genetic mutations. Your oncology team will test your tumor for this genetic alteration, which must be present in order to receive the medication.

How to Take Erdafitinib (Balversa™)

Erdafitinib comes as a tablet to take by mouth. It can be taken with or without food. Swallow the tablets whole; do not crush, break, or chew. If you vomit after taking erdafitinib, the next dose should be taken the next day. If you miss a dose, take the missed as soon as possible. Resume the regular daily dose schedule for erdafitinib the next day. Extra tablets should not be taken to make up for the missed dose.

The blood levels of this medication can be affected by certain foods and medications, so you should discuss your current medication list (including prescription medicines, over-the-counter drugs, and herbal products) and your diet with your provider before starting erdafitinib. Grapefruit, pomegranate and star fruit (and their juices) can interfere with erdafitinib and should be avoided. Certain medications can interfere with erdafitinib, so make sure your provider is aware of all the medications, vitamins and supplements you are taking, including but not limited to: carbamazepine, phenytoin, rifampin, azole antifungals, clarithromycin, sevelemar, and lanthanum.

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).

If a caregiver prepares your dose for you, they should consider wearing gloves or pour 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?

Erdafitinib 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 without 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 Erdafitinib**

There are a number of things you can do to manage the side effects of erdafitinib. 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:

**Electrolyte Abnormalities**

This medication can affect the normal levels of electrolytes (potassium, magnesium, calcium, phosphorous, etc.) in your body. In particular, erdafitinib can make levels of phosphorous in your body increase to unsafe levels. Your levels will be monitored using blood tests before and during treatment. If your levels become too high, your care team may prescribe specific medications, called phosphate binders, to decrease the levels of phosphorous in your body. If these levels become dangerously high, your provider may have you stop taking erdafitinib.

Your provider will recommend that you restrict your phosphorous intake to 600-800 mg daily. You should avoid large portions of foods that can make your phosphorous level increase, including:

- Fast foods.
- Packaged and convenience foods.
- Processed cheeses, such as American cheese and cheese spreads.
- Fresh or frozen meats that have added flavor.
- Sodas, flavored waters, bottled teas, energy or sports drinks.

Contact your provider right away if you have painful skin lesions, muscle cramps, or numbness and tingling around your mouth. Do not take any supplements without first consulting with your care team.

**Eye Problems**

While receiving erdafitinib, some patients may develop dry or inflamed eyes, irritation or damage to the cornea (clear covering of the eyeball), or disorders of the retina (thin layer of tissue that lines the back of the eye on the inside). Notify your healthcare team if you develop any eye pain or dryness, swelling, redness or any vision changes, including blurriness and sensitivity to light. You should use artificial tear substitutes, hydrating or lubricating eye gels or ointments at least every 2 hours during waking hours to help prevent dry eyes. During treatment with erdafitinib, your healthcare provider will send you to see an eye specialist.

**Mouth Ulcers (Mucositis)**

Certain cancer treatments can cause sores or soreness in your mouth and/or throat. Notify your oncology care team 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 with warm water mouth rinse (2 level teaspoons of baking soda or 1 level teaspoon of 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.

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

Diarrhea
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-caffeinated fluid a day to prevent dehydration.

Xerostomia (Dry Mouth)
This medication can cause xerostomia, also known as dry mouth. Xerostomia can be uncomfortable and can affect your speech, swallowing and dental health. Ways to manage this side effect include:

- Perform frequent oral hygiene with toothpaste containing fluoride.
- Floss once a day, if your care team says you can.
- Chew sugar free gum or suck on sugar free candy to stimulate saliva production.
- Rinse your mouth frequently to keep the mouth moist.
- Speak to your providers about over the counter and prescription gels and rinses that act as saliva replacement.

Speak to your provider if this side effect continues to be a problem.

Nail and Skin Changes
Erdafitinib has some unique nail and skin side effects that you may experience. Nails may develop "ridges" in them or fall off. This may appear several months after starting treatment, but can last for many months after treatment stops.

- 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.

Erdafitinib can also cause dry skin. Tips for managing your skin include:

- Use a thick, alcohol-free emollient lotion or cream on your skin at least twice a day, including right after bathing.
- Avoid sun exposure, as it can worsen the rash or cause a severe burn. Use a sunscreen with an SPF of 30 or higher and wear a hat and sunglasses to protect your head and face from the sun.
- Bathe/shower in cool or lukewarm (not hot) water and pat your skin dry.
- Use soaps, lotions and laundry detergents without alcohol, perfumes or dyes.
- Wear gloves to wash dishes or do housework or gardening.
- Drink plenty of water and try not to scratch or rub your skin.
- Notify your healthcare team if you develop a rash, as they can provide suggestions to manage the rash and/or prescribe a topical medication to apply to the rash or an oral medication.

If you develop peeling or blistering of the skin, notify your healthcare team right away.

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 or Taste Changes**

Nutrition is an important part of your care. Cancer treatment can affect your appetite and, in some cases, the side effects of treatment can alter your taste and 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.

**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.

**Constipation**

There are several things you can do to prevent or relieve constipation. Include fiber in your diet (fruits and vegetables), drink 8-10 glasses of non-alcoholic fluids a day, and keep active. A stool softener once or twice a day may prevent constipation. If you do not have a bowel movement for 2-3 days, you should contact your healthcare team for suggestions to relieve the constipation.

**Hand Foot Syndrome**

Hand foot syndrome (HFS) is a skin reaction that appears on the palms of the hands and/or the soles of the feet, as a result of certain chemotherapy agents being absorbed by the skin cells. HFS can begin as a mild tingling, numbness, pins-and-needles feeling, redness or pain or swelling of the hands and/or feet. This can then progress to painful swelling, blistering or peeling skin that can interfere with your ability to do normal activities. Be sure to let your oncology team know right away if you notice these symptoms, as they may need to adjust the chemotherapy dose or take a break to allow the skin to heal. Some tips to help prevent HFS include:

- Avoid tight shoes or socks.
- Keep hands and feet clean and dry.
- Avoid activities that put pressure on the palms or soles for 1 week after treatment.
- Apply an alcohol-free moisturizer liberally and often. (Avoid moisturizers with perfumes or scents).
- Avoid very hot water for baths and showers.

**Loss or Thinning of Scalp and Body Hair (Alopecia)**

Your hair may become thin, brittle, or may fall out. This typically begins two to three weeks after treatment starts. This hair loss can be all body hair, including pubic, underarm, legs/arms, eyelashes, and nose hairs. The use of scarves, wigs, hats and hairpieces may help. Hair generally starts to regrow soon after treatment is completed. Remember your hair helps keep you warm in cold weather, so a hat is particularly important in cold weather or to protect you from the sun.

**Nausea and/or Vomiting**

Talk to your doctor or nurse 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 antacids, (e.g. milk of magnesia, calcium tablets such as Tums), saltines, or ginger ale to lessen symptoms.

Call your doctor or nurse if you are unable to keep fluids down for more than 12 hours or if you feel lightheaded or dizzy at any
Muscle or Joint Pain/Aches and Headache
Your healthcare provider can recommend medications and other strategies to help relieve pain.

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 birth control is necessary during treatment and for at least 1 month after treatment. Even if your menstrual cycle stops or you believe you are not producing sperm, you could still be fertile and conceive. Women should not breastfeed during treatment and for 1 month after the final erdafitinib dose. Erdafitinib may impair fertility in females of reproductive potential. Talk with your provider concerning these risks.

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