

Erdafitinib

Care Team Contact Information: _____

Pharmacy Contact Information: _____

Diagnosis: _____

- This treatment is often used for a type of bladder and urinary tract cancer called urothelial cancer.
- It may also be used for other reasons.
- Your care team will perform a test for a certain type of abnormal FGFR gene to make sure that erdafitinib is right for you.

Goal of Treatment: _____

- Treatment may continue for a certain time period, until it no longer works, or until side effects are no longer controlled.

Treatment Regimen

Treatment Name	How the Treatment Works	How the Treatment is Given
Erdafitinib (ER-duh-FIH-tih-nib): Balversa (bal-VER-suh)	Slows down or stops the growth of cancer cells by blocking a specific protein that helps them survive.	Tablets taken by mouth.

Treatment Administration and Schedule

Your erdafitinib dosing instructions:

- Erdafitinib comes in 3 tablet strengths: 3 mg, 4 mg, and 5 mg.
- Your dose might differ, but the starting dose of erdafitinib is typically two 4 mg tablets (8 mg total dose) once daily.
- Take erdafitinib 1 time each day.
- Swallow erdafitinib tablets whole with or without food.
- Do not change your dose or stop taking erdafitinib unless your care team tells you to.
- Your care team may tell you to change your dose, temporarily stop, or completely stop taking erdafitinib if you develop certain side effects.
- If you miss a dose of erdafitinib, take the missed dose as soon as possible on the same day. Take your regular dose of erdafitinib the next day. Do not take more erdafitinib than prescribed to make up for the missed dose.
- If you vomit after taking erdafitinib, do not take another erdafitinib tablet. Take your regular dose of erdafitinib the next day.
- If you take too much erdafitinib, call your care team or go to the nearest hospital emergency room right away.

Storage and Handling of Erdaftinib

- Store erdaftinib tablets at room temperature between 68°F and 77°F (20°C and 25°C).
- People who are or may become pregnant should wear gloves when handling erdaftinib.
- Keep erdaftinib and all medicines out of the reach of children and pets.
- Ask your care team how to safely throw away any unused erdaftinib.

Appointments: Appointments may include regular check-ups with your care team, lab visits, and imaging tests. It's important to keep your appointments whenever you can. If you miss any appointments, call your care provider as soon as possible to reschedule your appointment.

Supportive Care to Prevent and Treat Side Effects

Description	Supportive Care Taken at Home
To help prevent or treat nausea and vomiting	<hr/> <hr/> <hr/>
To help prevent dry eyes	<hr/> <hr/> <hr/>
Other	<hr/> <hr/> <hr/>

Common Side Effects

Side Effect	Important Information
<p>Low Hemoglobin (Hgb) Count (Anemia)</p>	<p>Description: Hgb carries oxygen to your body’s tissues and removes carbon dioxide. Low Hgb (anemia) can make you feel weak, very tired, or look pale.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Aim for 7 to 8 hours of sleep each night. • Do not drive, operate heavy machinery, or do other dangerous activities if you are very tired. • Balance activity and rest — stay as active as you can, but rest when needed. • Eat a balanced diet and follow any nutrition or supplement advice from your care team. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Shortness of breath • Dizziness or fainting • Fast or irregular heartbeats • Sudden or severe headache
<p>Fatigue</p>	<p>Description: Fatigue is a constant and sometimes strong feeling of tiredness.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Routine exercise can help reduce fatigue. Talk with your care team to find the right type and amount of activity for you. • Ask family and friends for help with daily tasks and for emotional support. • Try healthy ways to feel better, such as meditation, journaling, yoga, or guided imagery, to reduce anxiety and improve well-being. • Aim for 7 to 8 hours of sleep each night. Limit daytime naps to help you sleep better at night. • Do not drive, operate heavy machinery, or do other potentially dangerous activities if you are very tired. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Tiredness that affects your daily life or prevents you from doing normal activities • Tiredness that does not get better with rest • Dizziness or weakness along with severe tiredness

<p>Low Appetite</p>	<p>Description: Loss of appetite can lead to weight loss and low energy. Small changes in when and what you eat can help maintain strength and nutrition.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Be as active as you can. Do light physical activity before a meal (check with your care team before starting an exercise program). • Note times of day when your appetite is best and eat your largest meal then. • Eat 5–6 small meals or snacks each day. • Choose high-protein foods (beans, chicken, fish, meat, yogurt, tofu, eggs). Eat protein first during meals. • Choose higher-calorie foods (avoid “low-fat,” “fat-free,” or “diet” options when trying to gain/maintain weight). • If you feel full quickly, avoid drinking 30 minutes before a meal and drink liquids between meals; choose calorie-containing drinks rather than diet drinks. • Have a bedtime snack that’s easy to digest (for example, peanut butter and crackers). If you have reflux, wait at least 1 hour before lying down. • Try nutritious beverages (high-protein shakes or smoothies) if solid food is unappealing. • Ask your care team about liquid nutrition supplements and ways to add protein or calories (protein powder, yogurt, ice cream). <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Unintentional weight loss • Little or no appetite for several days • Excessive tiredness or low energy
<p>Taste Changes</p>	<p>Description: Taste changes, such as loss of taste or taste sensitivity, may occur. Foods that used to taste good may no longer be appealing or certain tastes, such as metallic tastes, may become more noticeable.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Choose appealing foods based on appearance and smell. • Use plastic utensils if food tastes metallic. • Add spices or juices to enhance food flavors. • Suck on mints or chew gum to improve taste. • Brush your teeth before and after eating with a soft toothbrush. • Avoid smoking. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Trouble eating • Weight loss

<p>Mouth Sores or Irritation (Stomatitis) and Dry Mouth</p>	<p>Description: Treatment can irritate the lining of the mouth. In some cases, this can cause redness, sores, pain, and swelling. Erdafitinib may also cause dry mouth.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Rinse your mouth after meals and at bedtime; rinse more often if sores develop. • Brush your teeth gently with a soft toothbrush or use a cotton swab after meals. • Use a mild, non-alcohol mouth rinse at least 4 times daily (after meals and at bedtime). Example: 1/8 teaspoon salt + 1/4 teaspoon baking soda in 8 oz warm water. • Avoid acidic, hot, spicy, rough, or crunchy foods and drinks that can irritate your mouth. • Avoid tobacco, alcohol, and alcohol-based mouthwash. • Your care team may prescribe medicines or mouth treatments to help with pain and healing. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Painful mouth sores or throat pain • Trouble eating or significant weight loss
<p>Diarrhea</p>	<p>Description: Diarrhea is loose, watery stools or more frequent bowel movements than usual. It can cause dehydration and weakness.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Keep track of how often you go to the bathroom each day. • Drink 8 to 10 glasses of water or other fluids daily, unless your care team tells you otherwise. • Eat small meals of mild, low-fiber foods (such as bananas, applesauce, potatoes, chicken, rice, and toast). • If you have diarrhea, avoid high-fiber foods (such as raw vegetables, fruits, and whole grains), gas-producing foods (such as broccoli and beans), dairy (such as milk and yogurt), and spicy, fried, or greasy foods. • Your care team may recommend an antidiarrheal medicine such as loperamide (Imodium). <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • 4 or more bowel movements than normal in 24 hours • Dizziness or lightheadedness while having diarrhea • Signs of dehydration (very thirsty, dry mouth, dizziness, or dark urine) • Bloody diarrhea

<p>Liver Problems</p>	<p>Description: Treatment can cause liver injury. Your care team may check your liver with blood tests before and during treatment.</p> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Yellowing of your skin or the white part of your eyes (jaundice) • Severe nausea or vomiting • Pain on the right side of your stomach area (abdomen) • Dark, tea-colored urine • Bleeding or bruising more easily than normal
<p>Kidney Problems</p>	<p>Description: Treatment can cause kidney problems, including damage to the kidneys and decreased kidney function. Your care team will monitor your kidney function during treatment.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Drink 8 to 10 glasses of water or other fluids each day, unless your care team tells you otherwise. • Your care team may give you fluids and electrolytes with your treatment. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Decrease in your amount of urine • Blood in your urine • Swelling of your ankles • Loss of appetite
<p>Eye Problems</p>	<p>Description: Eye problems include dry or inflamed eyes, inflamed cornea (front part of the eye), and disorders of the retina, an internal part of the eye.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Use artificial tear substitutes, hydrating or lubricating eye gel or ointments at least every 2 hours during waking hours to help prevent dry eyes. • During treatment with erdafitinib, your care team may send you to see an eye specialist. <p>Talk to your care team if you have:</p> <p>New or worsening blurred vision Loss of vision or other visual changes</p>

<p>Hand-Foot Skin Reaction (HFSR)</p>	<p>Description: HFSR causes dryness, thickening, calluses, blisters, or cracking of the skin on the palms of your hands and soles of your feet. HFSR can lead to a loss of fingerprints, which could impact your identification.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Keep hands and feet moisturized with a non-scented moisturizing cream. • Applying urea 10% or 20% cream twice daily to the affected area may be helpful. • Avoid exposure to hot water on the hands and feet in showers or baths, or when doing dishes, as this may dry out the skin. • Avoid tight-fitting shoes or socks. • Avoid excessive rubbing of hands and feet unless applying lotion. • Wear gloves when working with your hands. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Painful blisters or calluses on your hands or feet
<p>Nail Problems</p>	<p>Description: Nails may become more brittle, thinner, and could change color during treatment.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Keep your fingernails and toenails trimmed short. • Wear cotton gloves when working. When cleaning or washing dishes, use cotton-lined rubber gloves to keep your hands from becoming dry and irritated. Do not use unlined rubber gloves because they seal in sweat and irritate the skin. • Avoid manicures, pedicures, and artificial nails, which may increase the risk of infection. • Do not bite your nails or pick at your cuticles. • Nail polish can help strengthen and may protect nails. To take off polish, use "oily" remover to prevent drying. • Soak your hands in natural oils (such as olive oil) to relieve dryness. • Wear loose-fitting shoes with cushioned cotton socks. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Pain related to nail changes • Fingernails or toenails that separate from the nail bed

<p>High Phosphate Levels in Your Blood (Hyperphosphatemia) and Buildup of Minerals in Different Tissues in Your Body</p>	<p>Description: Treatment may cause high levels of phosphate in your blood. This may lead to the buildup of minerals, such as calcium, in different tissues in your body. Your care team will perform blood tests to check you for these changes and will treat you if needed.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Read the Nutrition Facts on your food and drink label. • Eat or drink no more than 600 mg to 800 mg of phosphate per day. • Start a low-phosphate diet (limit dairy, cola, nuts, organ meats, and processed foods). • Stay well hydrated. • Avoid phosphate-containing laxatives or supplements. • Your care team may prescribe changes in your diet or phosphate-lowering therapy (such as sevelamer (Renvela) or calcium carbonate (Tums)). <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Muscle cramps, spasms, or numbness/tingling • Severe itching or new skin changes • Bone or joint pain • New or worsening irregular heartbeat, dizziness, or fainting • Little or no urine output
<p>Low Sodium Levels in Your Blood (Hyponatremia)</p>	<p>Description: Treatment may cause low levels of sodium in your blood. Your care team will perform blood tests to check you for these changes and will treat you if needed.</p> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • New or worsening confusion, drowsiness, or trouble thinking • Severe headache or nausea/vomiting • Seizures or fainting • Sudden weakness, unsteadiness, or trouble walking • Difficulty breathing

Before starting treatment, ask your care team when to call 9-1-1 or seek emergency help. If you experience any new, worsening, or uncontrolled side effects, contact your care team immediately.

Intimacy, Fertility, Pregnancy, and Breastfeeding

- Treatment may **change how you feel about intimacy and your body**. However, physical closeness—such as holding hands and hugging—remains safe. It is common to have questions about intimacy. If needed, talk to your care team for guidance.
- Treatment may affect your **ability to have children**. It may damage your reproductive organs or stop them from working. If you are worried about fertility, talk to your care team before starting treatment.
- Treatment may **harm an unborn baby**.
 - If you are able to become pregnant, take a pregnancy test before starting treatment.
 - Use an effective method of birth control during treatment and for 1 month after your last dose of erdafitinib.
 - If you think you might be pregnant or if you become pregnant, tell your care team right away.
 - If your partner is able to become pregnant, use an effective method of birth control—such as condoms—during treatment and for 1 month after your last dose of erdafitinib.
- **Do NOT breastfeed** during treatment and for 1 month after your last dose of erdafitinib.

Additional Information

- **Tell your care team about all the medicines you take.**
This includes prescriptions, over-the-counter drugs, vitamins, and herbal products. Before starting any new medicine, supplement, or vaccine, ask your care team first.
- **This Patient Education Sheet may not describe all possible side effects.**
Call your care team for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Notes

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Scan the QR code below to access this education sheet.



Important notice: The Association of Cancer Care Centers (ACCC), Hematology/Oncology Pharmacy Association (HOPA), Network for Collaborative Oncology Development & Advancement, Inc. (NCODA), and Oncology Nursing Society (ONS) have collaborated in gathering information for and developing this patient education guide. This guide represents a brief summary of the medication derived from information provided by the drug manufacturer and other resources.

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