

ORAL CANCER TREATMENT EDUCATION



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ERDAFITINIB

Name of your medication

Generic name — erdafitinib (ER-duh-FIH-tih-nib)

Brand name — Balversa® (bal-VER-sah)

Common uses

Erdafitinib is used to treat bladder cancer that has a genetic mutation called fibroblast growth factor receptor (FGFR).

Erdafitinib may also be used for other treatments.

Dose and schedule

Taking erdafitinib as instructed is important to allow your treatment to be as effective as possible, so here are some key points to remember.

- Your dose may vary, but the usual dose of erdafitinib is 8 milligrams (8 mg) to be taken by mouth at a scheduled time once a day. Your doctor may increase your dose to 9 milligrams (9 mg) daily after the first few weeks of treatment.
- Erdafitinib can be taken with or without food, but at the same time each day.
- Erdafitinib should be taken whole and not crushed, cut, or dissolved. If you are unable to swallow erdafitinib, talk to your care provider or pharmacist for possible options.
- If you miss a dose of erdafitinib, follow these guidelines:
 - Take the missed dose as soon as possible on the same day.
 - Do not take two doses at one time.
 - Be sure to write down if you miss a dose, and let your care provider know about any missed doses.

Drug and food interactions

- Erdafitinib has many drug interactions. Please inform your care providers of all prescription medications, over-the-counter medications, vitamins, and herbal products.
- Grapefruit or grapefruit juice may interact with erdafitinib; avoid eating or drinking this during treatment with erdafitinib.
- Talk with your care provider or pharmacist before taking new medications or supplements, or receiving any vaccines.
- For the first three weeks while taking erdafitinib, limit phosphate intake to 600 to 800 mg per day and avoid medications that can raise phosphate levels. Examples include potassium phosphate supplements, vitamin D supplements, antacids, and phosphate-containing enemas or laxatives. Talk to your healthcare provider about other medications that may also contain phosphate.

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Storage and handling

Handle erdafitinib with care. Just like when chemotherapy is given into the vein, this drug can be toxic, and exposure of the drug to others should be limited.

- ❑ Store erdafitinib at room temperature (68°F–77°F) in a dry location away from light.
- ❑ Keep erdafitinib out of reach of children and pets.
- ❑ Leave erdafitinib in the provided packaging until it is ready to be taken.
- ❑ Whenever possible, you should give erdafitinib to yourself and follow the steps below. If a family member, friend, or caregiver needs to give the erdafitinib to you, they also need to follow these steps.
 1. Wash hands with soap and water.
 2. Put on gloves to avoid touching the medication. (Gloves are not necessary if you give the drug to yourself.)
 3. Gently transfer the erdafitinib from its package to a small medicine or other disposable cup.
 4. Administer the medicine immediately by mouth with water.
 5. Remove gloves and do not use them for anything else.
 6. Throw gloves and medicine cup in household trash.
 7. Wash hands with soap and water.
- ❑ A daily pill box or pill reminder is **not** recommended to be used with erdafitinib.
- ❑ If you have any unused erdafitinib, **do not** throw it in the trash and **do not** flush it down the sink or toilet. Talk to your care provider or pharmacist about proper disposal of erdafitinib.
- ❑ If you are traveling, put your erdafitinib's packaging in a sealed plastic bag. Ask your pharmacist if any additional travel precautions are needed.

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Side Effects of Erdafitinib

Below are common side effects that have been known to happen in about one third or more of patients taking erdafitinib are listed on the left side of this table. You **MAY NOT** experience these side effects. Options to help manage any side effects that do occur are included on the right side of this table. These should be discussed with your care provider. If you experience any side effect you cannot manage or that is not listed here, contact your care provider.

Possible Side Effect	Management
<p>Mouth irritation, mouth sores, or dry mouth</p>	<p>Practice good mouth care.</p> <ul style="list-style-type: none"> Rinse your mouth frequently. Brush your teeth with a soft toothbrush or cotton swab after meals. Use a mild non-alcohol mouth rinse at least four times a day (after eating and at bedtime). One example is a mixture of 1/8 teaspoon of salt and 1/4 teaspoon of baking soda in 8 ounces of warm (not hot) water. If you have sores in your mouth, avoid using tobacco products, alcohol, and mouthwashes that contain alcohol. <p>Call your care provider if you experience pain or sores in your mouth or throat.</p>
<p>Changes in electrolytes and other laboratory values</p> <ul style="list-style-type: none"> High phosphate levels Low sodium levels Low magnesium levels Decreased albumin 	<p>Changes in some lab values may occur and will be monitored by a simple blood test.</p> <ul style="list-style-type: none"> You may not feel any symptoms if the changes are mild, and they usually are not a sign of a serious problem. More severe changes may occur, which can be a sign of a serious problem. <p>Notify your care provider if you have any of the following:</p> <ul style="list-style-type: none"> Shortness of breath Chest discomfort Weakness or fatigue New aches and pains Headaches Dizziness Swelling of your legs or feet Red- or brown-colored urine

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Possible Side Effect	Management
Diarrhea (loose and/or urgent bowel movements)	<p>Monitor how many bowel movements you have each day.</p> <ul style="list-style-type: none"> • Drink 8–10 glasses of water or fluid each day unless your care provider has instructed you to limit your fluid intake. • Eat small, frequent meals throughout the day rather than a few large meals. • Eat bland, low-fiber foods, such as bananas, applesauce, potatoes, chicken, rice, and toast. • Avoid high-fiber foods, such as raw vegetables, raw fruits, and whole grains. • Avoid foods that cause gas, such as broccoli and beans. • Avoid lactose-containing foods, such as yogurt and milk. • Avoid spicy, fried, and greasy foods. <p>Contact your provider if either of the following occurs:</p> <ul style="list-style-type: none"> • The number of bowel movements you have in a day increases by four or more. • You feel dizzy or lightheaded. <p>Your care provider may recommend an over-the-counter medication called loperamide (Imodium®) to help with your diarrhea, but talk to your care provider before starting this medication.</p>
Fatigue	<p>You may be more tired than usual or have less energy.</p> <ul style="list-style-type: none"> • Stay as active as possible, but know it is okay to rest as needed. • Try to do some activity every day. • Plan your activities, and do them at a time of day when you feel a bit more energetic. • Avoid operating heavy machinery if you feel too tired.
Changes in kidney function	<p>Your kidney (renal) function will be checked periodically by a simple blood test. Contact your care provider if you notice any of the following.</p> <ul style="list-style-type: none"> • Decreased amount of urination • Unusual swelling in your legs and feet
Nail changes	<p>Usually this change starts at the cuticle and may affect the skin around the nail.</p> <ul style="list-style-type: none"> • Biting, chewing, and picking at your nails can increase the risk of getting an infection. • Talk to your care provider if you notice any changes in your nails.
Changes in liver function	<p>Your liver function will be checked periodically by a simple blood test. Contact your care provider if you notice any of the following.</p> <ul style="list-style-type: none"> • Yellowing of the skin or whites of your eyes • Dark or brown urine • Bleeding or bruising

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Possible Side Effect	Management
<p>Decreased appetite or weight loss</p>	<ul style="list-style-type: none"> • Talk to your care provider if you notice a decrease in weight while taking this medication. • When you do not feel like eating, try the following: <ul style="list-style-type: none"> – Eat small frequent meals instead of three large meals each day. – Keep snacks nearby so you can eat when you feel hungry. – Use liquid nutritional supplements. – Drink 8–10 glasses of water or fluid each day, especially if you are not eating, unless your care provider has instructed you to limit your fluid intake.
<p>Taste changes</p>	<p>Some people experience a metallic or bitter taste in their mouth. To help with taste changes, try the following:</p> <ul style="list-style-type: none"> • Choose and prepare foods that look and smell good to you. • Use plastic utensils if food tastes like metal. • Flavor foods with spices to change taste. • Suck on mints or chew gum to mask taste. • Brush teeth before and after eating with a soft bristle toothbrush. • Avoid smoking. <p>Notify your doctor if you are having trouble eating or are losing weight.</p>
<p>Decreased hemoglobin, part of the red blood cells that carry iron and oxygen</p>	<p>Your hemoglobin should be monitored by a simple blood test. When your hemoglobin is low, you may notice that you get tired or fatigued more easily.</p> <ul style="list-style-type: none"> • Try to get 7–8 hours of sleep per night. • Avoid operating heavy machinery if you feel too tired. • Find a balance between work and rest. • Stay as active as possible, but know that it is okay to rest as needed. • You might notice that you are more pale than usual. <p>Let your health care provider know right away if you experience any of the following:</p> <ul style="list-style-type: none"> • Shortness of breath • Dizziness • Palpitations
<p>Rash or dry skin</p>	<ul style="list-style-type: none"> • Keep your skin moisturized with creams and moisturizing lotions to decrease the risk of rash or itchiness, and wear loose-fitting clothing. • Avoid using perfumes and cologne because these products may increase rash symptoms. • Avoid being in the heat for long periods of time. • Your provider may recommend an over-the-counter antihistamine or a topical cream. <p>If your rash or itching continues to worsen, contact your care provider.</p>

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Serious side effects of erdafitinib

- ❑ Erdafitinib may cause eye problems. Eye problems include dry or inflamed eyes, inflamed cornea (front part of the eye), and problems of the retina (an internal part of the eye). Tell your care team right away if you develop blurred vision, loss of vision, or visual changes. You should use artificial tears (hydrating or lubricating eye gels or ointments) at least every two hours during waking hours to help prevent dry eyes. During treatment with erdafitinib, your care provider will send you to see an eye specialist.

If you experience ANY uncontrolled side effect, call your physician or healthcare center immediately:

(INSTITUTIONAL CONTACT INFO)

Handling body fluids and waste

Since erdafitinib remains in your body for several days after it is taken, some of the drug may be present in urine, stool, sweat, or vomit. Once you have started to take erdafitinib, it is important to know the following instructions every day for as long as your treatment lasts. This is to keep yourself, loved ones, and the environment as safe as possible.

- ❑ Pregnant women should avoid touching anything that may be soiled with body fluids from the patient.
- ❑ Toilet and septic systems
 - You may use the same toilet, septic tank, and/or sewer that you usually use. If you have a low-flow toilet, close the lid and flush twice to ensure all waste has been discarded.
 - If the toilet or toilet seat becomes soiled with urine, stool, or vomit, clean the surfaces before other people use the toilet.
 - Wash hands with soap and water after using the toilet.
- ❑ If you need a bedpan, be sure your caregiver knows to wear gloves to assist with cleanup and to wash the bedpan with soap and water every day.
- ❑ If you do not have good control of bladder or bowels, use a disposable pad with a plastic back, a diaper, or a sheet to absorb body waste.
- ❑ Wash any skin that has been exposed to body waste or erdafitinib with soap and water.
- ❑ Linens or clothing that are soiled with body fluids or body waste should be washed separately from other linens and clothing. If you do not have a washer, place the soiled linens in a plastic bag until they can be washed.
- ❑ Wash hands with soap and water after touching linens or clothing that may be soiled with body fluids.

Pregnancy, sexual activity, and contraception

- ❑ Women should not become pregnant and men should not get a partner pregnant while taking erdafitinib. Men and women of childbearing age and potential should use effective contraception during therapy and for a minimum of 1 month after the last dose of erdafitinib.
- ❑ Effective contraception could include 1 or more of the following: oral contraceptive, barrier methods, etc.
- ❑ Do not breastfeed while taking erdafitinib and for 1 month after the last dose of erdafitinib.
- ❑ Please inform your care provider if you become pregnant.
- ❑ It is safe to hug and kiss. Special precautions may be needed for sexual activity while on oral chemotherapy, and you are encouraged to ask your care provider.

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Obtaining medication

- Talk with your care provider about the process for obtaining your erdafitinib.

_____ (PHARMACY OR SPECIALTY PHARMACY CONTACT INFO)

Additional resources

Product website: <https://www.balversa.com>

Product prescribing information: <https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/BALVERSA-pi.pdf>

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Additional instructions

Important notice: The Association of Community Cancer Centers (ACCC), Hematology/Oncology Pharmacy Association (HOPA), National Community Oncology Dispensing Association, 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. This guide does not cover all existing information related to the possible uses, directions, doses, precautions, warnings, interactions, adverse effects, or risks associated with this medication and should not substitute for the advice of a qualified healthcare professional. Provision of this guide is for informational purposes only and does not constitute or imply endorsement, recommendation, or favoring of this medication by ACCC, HOPA, NCODA, or ONS, who assume no liability for and cannot ensure the accuracy of the information presented. The collaborators are not making any representations with respect to the medications whatsoever, and any and all decisions, with respect to such medications, are at the sole risk of the individual consuming the medication. All decisions related to taking this medication should be made with the guidance and under the direction of a qualified healthcare professional.

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