

Erdafitinib (Balversa)

About This Medicine

ERDAFITINIB (ER da FI ti nib) treats bladder cancer and kidney cancer. It works by blocking a protein that causes cancer cells to grow and multiply. This helps to slow or stop the spread of cancer cells. It is given orally (by mouth).

This medicine may be used for other purposes; ask your care team if you have questions.

Possible Side Effects

- Decrease in red blood cells. This may make you feel more tired.
- Dry eyes
- Accumulation of fluid under the retina (thin membrane that covers the back of the eye)
- Soreness of the mouth and throat. You may have red areas, white patches, or sores in your mouth that hurt.
- Dry mouth
- Constipation (unable to move bowels)
- Diarrhea (loose bowel movements)
- Tiredness
- Changes in your liver function
- Decreased appetite (decreased hunger)
- Electrolyte changes
- Changes in the way food and drinks taste
- Changes in your kidney function
- Hair loss may happen. Hair loss is often temporary, although with certain medicine, hair loss can sometimes be permanent. Hair loss may happen suddenly or gradually. If you lose hair, you may lose it from your head, face, armpits, pubic area, chest, and/or legs. You may also notice your hair getting thin.
- Dry skin
- Changes in your nails and/or nail loss
- Hand-foot syndrome. The palms of your hands or soles of your feet may tingle, become numb, painful, swollen, or red.

Note: Each of the side effects above was reported in 20% or greater of people treated with erdafitinib. All possible side effects are not included. Your side effects may be different depending on your cancer

diagnosis, condition, or if you are receiving other medicines in combination. Please discuss any concerns or questions with your care team.

Warnings and Precautions

- Blurred vision or other changes in eyesight such as retinal detachment (thin membrane that covers the back of the eye separates from the eyeball), dry or inflamed eyes. Eye exams are recommended during your treatment.
- Increased phosphate level in your blood. You may require phosphate lowering treatment such as medicines and/or a low phosphate diet.

Note: *Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your care team.*

How to Take Your Medicine

- Swallow the medicine whole with or without food.
- **Missed dose:** If you miss a dose, take it as soon as you think about it on the same day and return to your next dose at the regular time the next day. Do not replace a vomited dose. Do not take 2 doses at the same time and do not double up on the next dose.
- **Overdosage:** If you think you have taken too much of this medicine contact a poison control center or emergency room at once.
- **Handling:** Wash your hands with soap and water, before and after handling your medicine. Your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- This medicine may be present in the urine, stool and other body fluids such as blood, vomit, semen, and vaginal fluids. Take precautions to prevent others from coming in contact with your medicine or your body fluids. Follow safety precautions during your treatment and for as long as directed by your care team after your treatment. If you take a pill each day, follow these precautions every day.
- **Storage:** Store this medicine in the original container at room temperature. Keep out of the reach of children and pets.
- **Disposal of unused medicine:** Do not flush any expired and/or unused medicine down the toilet or drain unless you are specifically instructed to do so on the medicine label. Some facilities have take-back programs and/or other options. If you do not have a take-back program in your area, then please discuss with your care team how to dispose of unused medicine.

Treating Side Effects

- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities.
- Drink enough fluids to keep your urine pale yellow.
- If you have diarrhea, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).
- Mouth care is very important. Your mouth care should consist of routine, gentle cleaning of your teeth or dentures and rinsing your mouth with a mixture of 1/2 teaspoon of salt in 8 ounces of water



or 1/2 teaspoon of baking soda in 8 ounces of water. This should be done at least after each meal and at bedtime.

- If you have mouth sores, avoid mouthwash that has alcohol. Also avoid alcohol and smoking because they can bother your mouth and throat.
- Sugar-free hard candies and chewing gum can keep your mouth moist.
- Taking good care of your mouth may help food taste better and improve your appetite.
- If you are not able to move your bowels, check with your care team before you use enemas, laxatives, or suppositories.
- If you have diarrhea, eat low-fiber foods that are high in protein and calories and avoid foods that can irritate your digestive tracts or lead to cramping.
- Ask your care team about medicines that are available to help stop or lessen constipation and/or diarrhea.
- To help with decreased appetite, eat small, frequent meals. Eat foods high in calories and protein, such as meat, poultry, fish, dry beans, tofu, eggs, nuts, milk, yogurt, cheese, ice cream, pudding, and nutritional supplements.
- Consider using sauces and spices to increase taste. Daily exercise, with your care team's approval, may increase your appetite. If you feel too tired to exercise vigorously, try taking a short walk.
- To help with hair loss, wash with a mild shampoo and avoid washing your hair every day. Avoid coloring your hair.
- Avoid rubbing your scalp, pat your hair or scalp dry.
- Limit your use of hair spray, electric curlers, blow dryers, and curling irons.
- If you are interested in getting a wig, talk to your care team and they can help you get in touch with programs in your local area.
- If you have dry eyes, you should use artificial tears, hydrating or lubricating eye gels, at least every 2 hours during waking hours to help prevent or treat dry eyes. Ask your care team for more information about which product they recommend for you.
- Moisturize your skin and your nails several times a day. Keeping your nails moisturized may help with brittleness.
- Avoid sun exposure and apply sunscreen routinely when outdoors.
- If you get a rash do not put anything on it unless your care team says you may. Keep the area around the rash clean and dry. Ask your care team for medicine if your rash bothers you.
- Use a gentle, unscented lotion to keep your hands and feet soft. A cream with 10% or 20% urea may help. Don't rub your hands or feet too much.
- Try not to put your hands or feet in hot water, like baths, showers, or washing dishes. Wear gloves when doing work with your hands. Avoid tight shoes or socks.

Food and Medicine Interactions

- This medicine may interact with grapefruit and grapefruit juice. Talk to your care team as this could make side effects worse.
- Check with your care team about all other prescription medicines and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs, and others) you are taking before starting this medicine as there are known medicine interactions with erdafitinib. Also, check with your care team before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.



- This medicine may interact with St. John's Wort and may lower the levels of the medicine in your body, which can make it less effective.

When to Call Your Care Team

Call your care team if you have any of these symptoms and/or any new or unusual symptoms:

- Blurred vision or other changes in eyesight
- Dry and/or itchy eye
- Tiredness that interferes with your daily activities
- Feeling dizzy or lightheaded
- Pain and/or dryness in your mouth or throat that makes it hard to eat, drink, or swallow
- No bowel movement in 3 days or when you feel uncomfortable
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
- Changes in the way food and drink taste that is causing a loss of appetite
- Lasting loss of appetite or rapid weight loss of five pounds in a week
- Decreased or very dark urine
- Signs of possible liver problems: dark urine, pale bowel movements, pain in your abdomen, feeling very tired and weak, unusual itching, or yellowing of the eyes or skin
- Signs of high phosphate: muscle cramps and/or numbness or tingling around your mouth
- Painful, red, or swollen areas on your hands or feet
- Numbness and/or tingling of your hands and/or feet
- Signs of inflammation/infection (redness, swelling, pain) of the tissue around your nails.
- Dry skin that is bothersome

Reproduction Warnings

- **Pregnancy warning:** This medicine can cause serious birth defects. If you can become pregnant, use birth control while taking this medicine and for 1 month after the last dose. If you can get your partner pregnant, use birth control while taking this medicine and for 1 month after the last dose. Tell your care team right away if you think you might be pregnant or think your partner might be pregnant.
- **Breastfeeding warning:** Do not breastfeed while taking this medicine and for 1 month after the last dose.
- **Fertility warning:** This medicine may affect your ability to have children in the future. If you plan to have children, talk with your care team.

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