

Erdafitinib (Balversa)

About This Medicine

Erdafitinib is used to treat cancer. It is given orally (by mouth).

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. 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 patients 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 medical 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 medical 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.
- **Handling:** Wash your hands with soap and water, before and after handling your medicine. Caretakers should not handle your medicine with bare hands and should wear latex gloves.
- Cytotoxic medicines leave the body through urine and stool, but they can also be present in 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 health care provider after your treatment. If you take a cytotoxic pill each day, follow these precautions every day.
- **Storage:** Store this medicine in the original container at room temperature.
- **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 nurse or your doctor 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 doctor or nurse 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 doctor or nurse 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 doctor'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 nurse 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 nurse or doctor 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 doctor or nurse says you may. Keep the area around the rash clean and dry. Ask your doctor for medicine if your rash bothers you.

Food and Medicine Interactions

- This medicine may interact with grapefruit and grapefruit juice. Talk to your doctor as this could make side effects worse.
- Check with your doctor or pharmacist 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 doctor or pharmacist 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 the Doctor

Call your doctor or nurse 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
- If you think you may be pregnant or may have impregnated your partner

Reproduction Warnings

- **Pregnancy warning:** This medicine can have harmful effects on the unborn baby. Women of childbearing potential should use effective methods of birth control during your cancer treatment and for 1 month after stopping treatment. Men with female partners of childbearing potential should use effective methods of birth control during your cancer treatment and for 1 month after stopping treatment. Let your doctor know right away if you think you may be pregnant or may have impregnated your partner.
- **Breastfeeding warning:** Women should not breastfeed during treatment and for 1 month after stopping treatment because this medicine could enter the breast milk and cause harm to a breastfeeding baby.
- **Fertility warning:** In women, this medicine may affect your ability to have children in the future. Talk with your doctor or nurse if you plan to have children. Ask for information on egg banking.

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