

## Erdafitinib (Balversa®)

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### About This Drug

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.
- Decrease in a blood protein called albumin
- Dry eyes
- Soreness of the mouth and throat. You may have red areas, white patches, or sores in your mouth that hurt.
- Dry mouth
- Nausea
- Constipation (unable to move bowels)
- Diarrhea (loose bowel movements)
- Pain in your abdomen
- Tiredness
- Changes in your liver function
- Decreased appetite (decreased hunger)
- Electrolyte changes
- Muscle and bone pain
- 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-and-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. Not all possible side effects are included above.

## Warnings and Precautions

- Blurred vision or other changes in eyesight such as dry eye
- Increased phosphorus

**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 Medication

- 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. If you vomit a dose or miss a dose, contact your doctor. Do not take 2 doses at the same time and do not double up on the next dose.
- **Handling:** Wash your hands after handling your medicine, your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- This drug may be present in the saliva, tears, sweat, urine, stool, vomit, semen, and vaginal secretions. Talk to your doctor and/or your nurse about the necessary precautions to take during this time.
- **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 medication 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 plenty of fluids (a minimum of eight glasses per day is recommended).
- To help with nausea, eat small, frequent meals instead of three large meals a day. Choose foods and drinks that are at room temperature. Ask your nurse or doctor about other helpful tips and medicine that is available to help, lessen or stop these symptoms.
- 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.
- 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 throw up or 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).
- 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, diarrhea and/or nausea.
- 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.
- To help with hair loss, wash with a mild shampoo and avoid washing your hair every day.
- Avoid rubbing your scalp, pat your hair or scalp dry.
- Avoid coloring your hair.
- 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. You can also call the American Cancer Society at 800-ACS-2345 to find out information about the "Look Good, Feel Better" program close to where you live. It is a free program where women getting chemotherapy can learn about wigs, turbans and scarves as well as makeup techniques and skin and nail care.
- Ask your doctor on the use of artificial tears and/or lubricating gels to prevent dry eyes.
- 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.
- Keeping your pain under control is important to your well-being. Please tell your doctor or nurse if you are experiencing pain.

## Food and Drug Interactions

- This drug 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 drug 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.
- Avoid the use of St. John's Wort while taking erdafitinib as this may lower the levels of the drug 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:

- Fever of 100.4° F (38° C) or higher
- Chills
- Blurred vision or other changes in eyesight
- Dry and/or itchy eye
- Tiredness that interferes with your daily activities
- Feeling dizzy or lightheaded
- Pain in your mouth or throat that makes it hard to eat or drink
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- 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
- Pain in your abdomen that does not go away
- Pain that does not go away, or is not relieved by prescribed medicines
- Lasting loss of appetite or rapid weight loss of five pounds in a week
- Tiredness that interferes with your daily activities
- Decreased urine or very dark urine
- Signs of possible liver problems: dark urine, pale bowel movements, bad stomach pain, feeling very tired and weak, unusual itching, or yellowing of the eyes or skin
- Weight gain of 5 pounds in one week (fluid retention)
- Swelling of your legs, ankles and/or feet
- 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.
- If you think you may be pregnant or may have impregnated your partner

## Reproduction Warnings

- **Pregnancy warning:** This drug can have harmful effects on the unborn baby. Women of child bearing potential should use effective methods of birth control during your cancer treatment and for at least 1 month after treatment. Men with female partners of child bearing potential should use effective methods of birth control during your cancer treatment and for at least 1 month after your cancer 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 breast feed during treatment and for 1 month after treatment because this drug could enter the breast milk and cause harm to a breastfeeding baby.
- **Fertility warning:** In women, this drug 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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