

Vandetanib (Caprelsa)

About This Medicine

VANDETANIB (van DET a nib) treats thyroid 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

- Nausea
- Diarrhea (loose bowel movements)
- Colitis- inflammation (swelling) in the colon. Symptoms are diarrhea, stomach cramping, and sometimes blood in the bowel movements
- Pain in your abdomen
- Decreased appetite (decreased hunger)
- Headache
- Upper respiratory tract infection
- Rash
- Pimple-like rash
- High blood pressure

Note: Each of the side effects above was reported in greater than 20% of people treated with vandetanib. 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

- Stroke, which can be life-threatening. Symptoms of a stroke may be sudden numbness or weakness of your face, arm, or leg, especially on one side of your body; sudden confusion, trouble speaking or understanding; sudden trouble seeing in one or both eyes; sudden trouble walking, feeling dizzy, loss of balance or coordination; or sudden bad headache with no known cause. **If you have any of these symptoms for 2 minutes, call 911.**

- Swelling in the brain that is usually reversible. Symptoms can be sudden (acute) and may include a headache, confusion, changes in eyesight, extreme tiredness/coma, and/or seizures. **If you start to have any of these symptoms let your care team know right away.**
- Changes in heart function such as serious and life-threatening abnormal heartbeat and congestive heart failure - your heart is not pumping blood as well as it should be, and fluid can build up in your body.
- Inflammation and/or scarring of the lungs, which can be life-threatening. You may have a cough and/or trouble breathing.
- Severe diarrhea
- Serious abnormal bleeding, which can be life-threatening – symptoms may be coughing up blood, throwing up blood (may look like coffee grounds), red or black tarry bowel movements, abnormally heavy menstrual flow, nosebleeds, or any other unusual bleeding.
- Severe allergic skin reaction, which can be life-threatening. You may develop blisters on your skin that are filled with fluid or a severe red rash all over your body that may be painful. You may be sensitive to the sun for up to 4 months after discontinuing this medicine. You may get a skin rash/reaction if you are in the sun or are exposed to sun lamps and tanning beds.
- Severe high blood pressure
- Changes in your thyroid function
- Changes in your kidney function, which can cause kidney failure
- Slow wound healing
- Osteonecrosis of the jaw. This is a breakdown of the jawbone. It is a serious but rare health problem.

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

Important Information

- You will need to sign up for a special program called Caprelsa REMS when you start taking this medicine. Your care team will help you get started.
- Vandetanib may cause slow wound healing. It should not be given within 1 month of planned surgery and for at least 2 weeks and until adequate wound healing following major surgery. If you must have emergency surgery or have an accident that results in a wound, tell your care team that you are on vandetanib.
- This medicine may impair your ability to drive or use machinery. Use caution and talk to your care team about any precautions you may need to take.

How to Take Your Medicine

- Swallow the medicine whole with water, with or without food. Do not crush or chew tablets.
- If you have difficulty swallowing, dissolve tablet in 2 ounces of noncarbonated water (no other liquid should be used) while stirring for 10 minutes. The tablet will not completely dissolve. Swallow immediately; mix any leftover medicine with 4 ounces of noncarbonated water and swallow.



- **Missed dose:** If you miss a dose and your next dose is due in more than 12 hours, then take the missed dose, and take your next dose at the regular time. If you miss a dose, and your next dose is due in less than 12 hours, then skip the missed dose and take your next dose at the regular time.
- **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.
- If you get any of the contents of a crushed tablet on your skin, you should wash the area of the skin well with soap and water right away. Call your care team if you get a skin reaction.
- 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

- Drink enough fluids to keep your urine pale yellow.
- 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).
- 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 medicine that can lessen or stop your diarrhea.
- To help with nausea and vomiting, eat small, frequent meals instead of three large meals a day. Choose foods and drinks that are at room temperature. Ask your care team about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- 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.
- Keeping your pain under control is important to your well-being. Please tell your care team if you are experiencing pain.
- 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.
- Limit sun exposure and cover up when you are out in the sun during your treatment and for at least 4 months after treatment. Use sunscreen with SPF 30 or higher when you are outdoors even for a short time. Wear wide-brimmed hats, long-sleeved shirts, and pants. Keep your neck, chest, and back covered.
- Tell your dentist and/or oral surgeon that you are taking this medicine. You should not have major dental surgery while on this medicine. Talk to your care team about any dental problems you may have before starting this medicine. You may need to see your dentist to have a dental exam and fix



any dental problems before starting this medicine. Take good care of your teeth. Make sure you see your dentist for regular follow-up appointments.

Food and Medicine Interactions

- There are no known interactions of vandetanib with food.
- 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 vandetanib. 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.
- Avoid the use of St. John's Wort while taking vandetanib as this 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:

- Fever of 100.4° F (38° C) or higher
- Chills
- A headache that does not go away
- Blurry vision or other changes in eyesight
- Feeling dizzy or lightheaded
- Extreme tiredness and/or coma
- Confusion
- Symptoms of a seizure such as confusion, blacking out, passing out, loss of hearing or vision, blurred vision, unusual smells, or tastes (such as burning rubber), trouble talking, tremors or shaking in parts or all of the body, repeated body movements, tense muscles that do not relax, and loss of control of urine and bowels. **If you or your family member suspects you are having a seizure, call 911 right away.**
- Symptoms of a stroke such as sudden numbness or weakness of your face, arm, or leg, especially on one side of your body; sudden confusion, trouble speaking or understanding, sudden trouble seeing in one or both eyes, sudden trouble walking, feeling dizzy, loss of balance or coordination; or sudden bad headache with no known cause. **If you have any of these symptoms for 2 minutes, call 911.**
- Pain in your chest
- Wheezing and/or trouble breathing
- Dry cough
- Coughing up yellow, green, or bloody mucus
- Feeling that your heart is beating fast or in a not normal way (palpitations)
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Throwing up more than 3 times a day
- Lasting loss of appetite or rapid weight loss of five pounds in a week
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy



- Blood in your stool (bright red, or black/tarry)
- Pain in your abdomen that does not go away
- Weight gain of 5 pounds in one week (fluid retention)
- Swelling of the legs, feet, or ankles
- Decreased or very dark urine
- Signs of abnormal bleeding such as coughing up blood, throwing up blood (may look like coffee grounds), easy bleeding or bruising, red or black tarry bowel movements, abnormally heavy menstrual flow, nosebleeds, or any other unusual bleeding
- Signs of low thyroid function: tiredness, unexplained weight gain, hair loss, dry skin, constipation, increased sensitivity to cold
- Flu-like symptoms: fever, headache, muscle and joint aches, and fatigue (low energy, feeling weak)
- A new rash and/or itching or a rash that is not relieved by prescribed medicines
- Develop sensitivity to sunlight/light
- Signs of osteonecrosis of the jaw such as pain, swelling or infection of the gums, loose teeth, poor healing of the gums, numbness, or the feeling that your jaw is heavy

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 4 months after the last dose. If you can get your partner pregnant, use birth control while taking this medicine and for 4 months 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 4 months after the last dose.
- **Fertility warning:** This medicine can affect your ability to have children in the future. If you plan to have children, talk with your care team.

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