

17.6 Pregnancy and Nursing

Patients of childbearing potential must be told to use effective contraception during therapy and for at least four months following their last dose of vandetanib.

Breast-feeding mothers are advised to discontinue nursing while receiving vandetanib therapy.

17.7 Drug Handling

Vandetanib tablets should not be crushed. Direct contact of crushed tablets with the skin or mucous membranes should be avoided.

17.8 Medication Guide

MEDICATION GUIDE

Tradename (phonetic spelling) Vandetanib Tablets

Read this Medication Guide before you start taking vandetanib and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or treatment.

What is the most important information I should know about vandetanib?

Vandetanib can cause a change in the electrical activity of your heart called QT prolongation, which can cause irregular heartbeats and that may lead to death. You should not take vandetanib if you have had a condition called long QT syndrome since birth.

Your healthcare provider should perform tests to check the levels of your blood potassium, calcium, magnesium, and thyroid-stimulating hormone (TSH) as well as the electrical activity of your heart with a test called an electrocardiogram (ECG). You should have these tests:

- Before starting vandetanib
- Regularly during vandetanib treatment:
 - 2 to 4 weeks after starting vandetanib
 - 8 to 12 weeks after starting vandetanib
 - Every 3 months thereafter
 - If your healthcare provider changes your dose of vandetanib
 - If you start taking medicine that causes QT prolongation
 - As instructed by your healthcare provider

Your healthcare provider may stop your vandetanib treatment for a while and restart you at a lower dose if you have QT prolongation.

Call your healthcare provider right away if you feel faint, light-headed, or feel your heart beating irregularly while taking vandetanib. These may be symptoms related to QT prolongation.

What is vandetanib?

Vandetanib is a prescription medicine used to treat medullary thyroid cancer that cannot be removed by surgery or that has spread to other parts of the body. It takes a long time to get rid of vandetanib from your body and you may be at risk for side effects related to vandetanib after you have stopped your treatment.

It is not known if vandetanib is safe and effective in children.

Who should not take vandetanib?

Do not take vandetanib if you have had QT prolongation.

What should I tell my healthcare provider before taking vandetanib?

Before you take vandetanib, tell your healthcare provider if you:

- have any heart problems, including a condition called congenital long QT syndrome.
- have an irregular heartbeat
- take or have stopped taking a medicine that causes QT prolongation
- have low blood levels of potassium, calcium, or magnesium
- have high blood levels of thyroid-stimulating hormone
- have high blood pressure
- have skin problems
- have a history of breathing problems
- have a recent history of coughing up blood or bleeding
- have diarrhea
- have liver problems
- have kidney problems
- have seizures or are being treated for seizures
- are pregnant or plan to become pregnant. Vandetanib can cause harm to your unborn baby. Talk to your healthcare provider if you are pregnant or plan to become pregnant.
 - If you are able to become pregnant, you should use effective birth control during your treatment with vandetanib and for at least 4 months after your last dose of vandetanib.
 - Talk to your healthcare provider about birth control methods to prevent pregnancy while you are taking vandetanib.

- are breastfeeding or plan to breastfeed. It is not known if vandetanib passes into your breast milk. You and your healthcare provider should decide if you will take vandetanib or breastfeed. You should not do both.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Vandetanib and other medicines may affect each other causing side effects.

Especially tell your healthcare provider if you take:

- St. John's Wort. You should not take St. John's Wort while taking vandetanib.
- certain medicines that can affect how your liver breaks down medicine
- a medicine for your heart

Ask your healthcare provider if you are not sure if your medicine is one listed above.

Do not take other medicines while taking vandetanib until you have talked with your healthcare provider or pharmacist.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take vandetanib?

- Take vandetanib exactly as your healthcare provider tells you to take it. Do not change your dose or stop taking vandetanib unless your healthcare provider tells you to.
- Vandetanib may be taken with or without food.
- Swallow vandetanib tablets whole with water.
- Do not crush or chew vandetanib tablets. If vandetanib tablets are accidentally crushed, contact with skin should be avoided. If contact occurs, wash affected areas well with water.
- If you cannot swallow vandetanib tablets whole:
 - place your dose of vandetanib in a glass that contains 2 ounces of noncarbonated water (no other liquids should be used).
 - stir the vandetanib tablet(s) and water mixture for about 10 minutes or until the tablet(s) are in very small pieces (the tablets will not completely dissolve).
 - swallow vandetanib and water mixture right away. If any
 - vandetanib and water mixture remains in the glass, mix with an additional 4 ounces of noncarbonated water and swallow the mixture to make sure that you take your full dose of vandetanib.
- If you miss a dose and your next dose is in:
 - less than 12 hours, take your next dose at the normal time. Do not make up for the missed dose
 - 12 hours or more, take the missed dose as soon as you remember. Take the next dose at the normal time

Call your healthcare provider right away if you take too much vandetanib.

- During treatment with vandetanib, your healthcare provider should check your blood and heart for side effects. See “What is the most important information I should know about vandetanib?”
- Your healthcare provider should check your blood pressure regularly during your treatment with vandetanib.

What should I avoid while taking vandetanib?

- Limit exposure to the sun. Vandetanib can make your skin sensitive to the sun. While taking vandetanib and for 4 months after stopping your vandetanib treatment, use sun block and wear clothes that cover your skin, including your head, arms and legs when you go outdoors.
- Use caution before driving or using machinery. Keep in mind vandetanib may make you feel tired, weak, or cause blurred vision.

What are the possible side effects of vandetanib?

Vandetanib may cause serious side effects, including:

- See “**What is the most important information I should know about vandetanib?**”
- **Serious skin reactions.**
Vandetanib can cause a serious skin reaction, called Stevens-Johnson syndrome or other serious skin reactions that may affect any part of your body. These serious skin reactions may be life threatening and you may need to be treated in a hospital. Call your healthcare provider right away if you experience any of these symptoms.
 - Skin rash or acne
 - Dry skin
 - Itching
 - Blisters on your skin,
 - Blisters or sores in your mouth
 - Peeling of your skin
 - Fever
 - Muscle or joint aches
 - Redness or swelling of your face, hands, or soles of your feet
- Breathing problems (interstitial lung disease)
- Vandetanib may cause a breathing problem called interstitial lung disease that can lead to death. Tell your healthcare provider right away if you experience sudden or worsening shortness of breath or cough.

- **Stroke.** Strokes have been reported in some people who have taken vandetanib and in some cases have caused death. Stop taking vandetanib and call your healthcare provider right away if you have symptoms of a stroke which may include:
 - numbness or weakness of the face, arm or leg, especially on one side of the body
 - sudden confusion, trouble speaking or understanding
 - sudden trouble seeing in one or both eyes
 - sudden trouble walking, dizziness, loss of balance or coordination
 - sudden, severe headache
- **Bleeding.** Bleeding can happen during your treatment with vandetanib. Tell your healthcare provider right away if you have severe bleeding while you are taking vandetanib.
- **Heart failure.** Vandetanib can cause heart failure that can lead to death. You may have to stop taking vandetanib if you have heart failure. Heart failure may not be reversible after stopping vandetanib. Your healthcare provider should monitor you for signs and symptoms of heart failure.
- **Diarrhea.** Diarrhea is often a symptom of medullary thyroid cancer. Vandetanib can also cause diarrhea or make diarrhea worse. Your healthcare provider should check your blood levels to monitor your electrolytes more frequently if you have diarrhea.
- **Thyroid hormones.** You can have changes in your thyroid hormone when taking vandetanib. Your healthcare provider should monitor your thyroid hormone levels while taking vandetanib.
- **High blood pressure (hypertension).** If you develop high blood pressure or your high blood pressure gets worse, your healthcare provider may lower your dose of vandetanib or tell you to stop taking vandetanib until your blood pressure is under control. Your healthcare provider may prescribe another medicine to control your high blood pressure.
- **Reversible Posterior Leukoencephalopathy Syndrome (RPLS).** A condition called reversible posterior leukoencephalopathy syndrome can happen while taking vandetanib. Call your healthcare provider right away if you have:
 - headaches
 - seizures
 - confusion
 - changes in vision
 - problems thinking

The most common side effects of vandetanib include:

- diarrhea
- rash
- acne
- nausea
- high blood pressure
- headache
- feeling tired
- loss of appetite
- stomach (abdominal) pain

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of vandetanib. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store vandetanib?

- Store vandetanib tablets at 59°F to 86°F (15°C to 30°C).
- Safely throw away medicine that is out of date or that you no longer need. Ask your pharmacist how to safely throw away vandetanib tablets.

Keep vandetanib and all medicines out of the reach of children.

General information about vandetanib.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use vandetanib for a condition for which it was not prescribed. Do not give vandetanib to other people, even if they have the same symptoms you have. It may harm them.

This Medication Guide summarizes important information about vandetanib. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about vandetanib that is written for health professionals.

For more information, go to www.vandetanib.com or call 1-800-236-9933.

What are the ingredients in vandetanib?

Active ingredient: vandetanib

Inactive ingredients:

- **Tablet core:** calcium hydrogen phosphate dihydrate, microcrystalline cellulose, crospovidone, povidone, and magnesium stearate
- **Tablet film-coat:** hypromellose 2910, macrogol 300, and titanium dioxide E171

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Distributed by:

AstraZeneca Pharmaceuticals LP
Wilmington, DE 19850

Issued 03-23-2011

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