

Important Safety Information, including Boxed WARNING, about CAPRELSA (Cont'd)

CAPRELSA may cause other serious side effects, including:

- **Serious skin reactions.** CAPRELSA can cause serious skin reactions, such as Stevens-Johnson syndrome and toxic epidermal necrolysis, or other serious skin reactions that may affect any part of your body. These serious skin reactions may be life threatening. Call your health care 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).** CAPRELSA may cause a breathing problem called interstitial lung disease that can lead to death. Tell your health care 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 CAPRELSA and in some cases have caused death. Stop taking CAPRELSA and call your health care 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 CAPRELSA. Tell your health care provider right away if you have severe bleeding while you are taking CAPRELSA
- **Heart failure.** CAPRELSA can cause heart failure that can lead to death. You may have to stop taking CAPRELSA if you have heart failure. Heart failure may not be reversible after stopping CAPRELSA. Your health care provider should monitor you for signs and symptoms of heart failure
- **Diarrhea.** Diarrhea is often a symptom of medullary thyroid cancer. CAPRELSA can also cause diarrhea or make diarrhea worse. Tell your health care provider right away if you develop diarrhea or your diarrhea gets worse
- **Thyroid hormones.** You can have changes in your thyroid hormone when taking CAPRELSA. Your health care provider may need to adjust your thyroid medication while you are taking CAPRELSA
- **High blood pressure (hypertension).** If you develop high blood pressure or your high blood pressure gets worse, your health care provider may lower your dose of CAPRELSA or tell you to stop taking CAPRELSA until your blood pressure is under control. Your health care 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 CAPRELSA. Call your health care provider right away if you have: headaches; seizures; confusion; changes in vision; problems thinking

Be sure to tell your health care provider about all your health conditions, including any heart problems. Also tell your health care provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Do not take other medicines while taking CAPRELSA until you have talked with your health care provider or pharmacist.

Tell your health care provider if you are pregnant or plan to become pregnant. CAPRELSA can cause harm to your unborn baby.

CAPRELSA can make your skin sensitive to the sun, so you should limit exposure to the sun. While taking CAPRELSA and for 4 months after stopping your CAPRELSA 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 that CAPRELSA may make you feel tired or weak, or cause blurred vision.

It takes a long time to get rid of CAPRELSA from your body and you may be at risk for side effects related to CAPRELSA after you have stopped your treatment.

Most Common Side Effects

The most common side effects of CAPRELSA include diarrhea (57%), rash (53%), acne (35%), nausea (33%), high blood pressure (33%), headache (26%), feeling tired (24%), upper respiratory tract infections (23%), loss of appetite (21%), and stomach (abdominal) pain (21%).

Approved Uses for CAPRELSA

CAPRELSA 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, and the tumors are growing or causing symptoms. Because of the risks associated with CAPRELSA, your health care provider should carefully consider whether to prescribe CAPRELSA for you if your tumors are growing slowly or if you are not having symptoms.

Please read [Prescribing Information, including Boxed WARNING](#).

Please read [Medication Guide](#).

This information does not take the place of talking to your health care provider about your medical condition or treatment.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. You may report side effects to the FDA at 1-800-FDA-1088. You may also contact Sanofi Genzyme at 1-800-745-4447, option 2.

This product information is intended for US audiences only.

CAPRELSA is a registered trademark of Sanofi Genzyme.