

Approved Use 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. 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. It is not known if CAPRELSA is safe and effective in children.

Questions to Ask Your Doctor

It's important to ask questions during your doctor visits so you can better understand your diagnosis and treatment. To prepare for your next appointment, print this guide out, add any other questions you may have, and take it with you.



Questions About Advanced Medullary Thyroid Cancer

- What is medullary thyroid cancer (MTC)?
- What are the signs and symptoms of MTC?
- Can anyone in my family get MTC?
- What is advanced medullary thyroid cancer (aMTC)?
- How is aMTC diagnosed?
- What stage of aMTC do I have and what does my stage mean?
- Can my aMTC be cured?
- What are my treatment options?
- What are the side effects of these treatments and what can I do to help manage them?
- How long will these side effects last?

My Notes

Questions About CAPRELSA

- How does CAPRELSA work?
- What are the side effects of CAPRELSA?
- Is CAPRELSA right for me?

Important Safety Information

CAPRELSA 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 CAPRELSA if you have had a condition called long QT syndrome since birth.

Your health care 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). These tests should be performed before starting CAPRELSA and regularly during CAPRELSA treatment.

Call your health care provider right away if you feel faint, light-headed, or feel your heart beating irregularly during your treatment with CAPRELSA. These may be symptoms related to QT prolongation.

CAPRELSA is only available through a restricted program called the CAPRELSA Risk Evaluation and Mitigation Strategy (REMS) Program. For more information about the CAPRELSA REMS Program, call 1-800-817-2722 or go to www.caprelsa.com.

Please see additional Important Safety Information throughout and click [here](#) for full Prescribing Information including Risk of SERIOUS SIDE EFFECTS, and Medication Guide.

Important Safety Information (Cont'd)



CAPRELSA may cause other serious side effects, including:

- **Severe skin reactions.** CAPRELSA can cause severe skin reactions that can lead to death, such as toxic epidermal necrolysis and Stevens-Johnson syndrome, or other serious skin reactions that may affect any part of your body. These severe skin reactions may be life threatening and you may need to be treated in a hospital. Tell your health care provider right away if you get any of these symptoms: skin rash or acne; dry skin; itching; blisters on your skin; redness or swelling of your face, hands, or soles of your feet; blisters or sores in your mouth; peeling of your skin; fever; muscle or joint aches
- **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, cough that does not go away (persistent) or fever.
- **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.** CAPRELSA can cause serious bleeding that can lead to death. Tell your health care provider right away if you have severe bleeding during treatment with 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 common with CAPRELSA and can be severe. Tell your health care provider right away if you develop diarrhea during treatment with CAPRELSA.
- **Thyroid hormones.** You can have changes in your thyroid hormone during treatment with CAPRELSA. Your healthcare provider should monitor your thyroid hormone levels during treatment with 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 get any of these symptoms: seizures; headaches; changes in vision; confusion; problems thinking.
- **Kidney problems.** CAPRELSA may cause problems with your kidneys, including kidney failure.
- **Wound healing problems.** Wounds may not heal properly during CAPRELSA treatment. Tell your healthcare provider if you plan to have any surgery before starting or during treatment with CAPRELSA.

The most common side effects of CAPRELSA include rash, acne, high blood pressure, nausea, headache, upper respiratory tract infections, decreased appetite, and stomach-area (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 of the possible side effects of CAPRELSA.

Before you take CAPRELSA, 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.

Females who are able to become pregnant: Tell your health care provider if you are pregnant or plan to become pregnant. CAPRELSA can cause harm to your unborn baby. Your healthcare provider must do a pregnancy test before you begin treatment with CAPRELSA. You must use effective birth control (contraception) during your treatment with CAPRELSA and for 4 months after your last dose of CAPRELSA. Talk to your healthcare provider about birth control methods that may be used during treatment with CAPRELSA.

Males with female partners who are able to become pregnant: You must use effective birth control during treatment with CAPRELSA and for 4 months after your last dose of CAPRELSA.

What should I avoid while taking CAPRELSA?

Limit exposure to the sun. CAPRELSA can make your skin sensitive to the sun. During treatment with CAPRELSA and for at least 4 months after stopping treatment with CAPRELSA, 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.

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.

Please see additional Important Safety Information throughout and click [here](#) for full Prescribing Information including Risk of SERIOUS SIDE EFFECTS, and Medication Guide.

CAPRELSA, Sanofi and Genzyme are registered in the US Patent and Trademark office.

©2024 Sanofi. All rights reserved.

sanofi