

Doctor Discussion Guide for TASIGNA

Is it time to talk with your doctor about switching to TASIGNA?

Although you may be taking medication for Philadelphia chromosome–positive chronic myeloid leukemia (Ph+ CML), there are reasons why it may be time to discuss switching to TASIGNA® (nilotinib) capsules with your doctor. Among them:

- **Drug intolerance:** You may no longer be able to tolerate the side effects of your current medication. Although some side effects can be managed, if they are too severe or damage your health, your doctor may need to change your medication
- **Lack of response:** You may not respond to treatment with your current medication
- **Drug resistance:** You may lose your response to your medication over time

Use this 3-step guide to see if it's time to discuss switching to TASIGNA with your doctor.

Step 1: Answer questions about your treatment

Step 2: Select questions to ask your doctor

Step 3: Share your discussion guide with your doctor

Step 1: Answer questions about your treatment

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Which of the following side effects have you experienced due to the medication you are taking for Ph+ CML? (Check all that apply)

- | | |
|---|-----------------------------------|
| <input type="checkbox"/> Nausea | <input type="checkbox"/> Diarrhea |
| <input type="checkbox"/> Muscle cramps | <input type="checkbox"/> Vomiting |
| <input type="checkbox"/> Rash | <input type="checkbox"/> Headache |
| <input type="checkbox"/> Dry skin | <input type="checkbox"/> Fatigue |
| <input type="checkbox"/> Other (add side effect here) _____ | |

Approved Uses

TASIGNA® (nilotinib) capsules is a prescription medicine used to treat:

- Adults with newly diagnosed Philadelphia chromosome–positive (Ph+) chronic myeloid leukemia (CML) in chronic phase
- Adults with Ph+ CML in chronic phase and accelerated phase who no longer benefit from, or did not tolerate, other treatment, including GLEEVEC® (imatinib)

Please see Important Safety Information, including the **Boxed WARNING** throughout.



2

How would you describe the level of the BCR-ABL protein in your blood based on your lab tests?

Note, the lower the number of BCR-ABL cells in your blood, the better. (Choose one)

- Going down steadily
- Down slightly
- About the same
- Up slightly
- Going up steadily
- Not sure about my BCR-ABL level

(Note: It may be a good idea to speak with your doctor about your most recent bloodwork results.)

Step 2: Select questions to ask your doctor

Check the questions below that you want to ask your doctor at your next appointment.

- I can no longer tolerate the side effects of my current medication for Ph+ CML. Is it time to change my dose or switch medications?
- I haven't seen much improvement in my test results. Has my current medication stopped working?

Add any other questions you'd like to ask:

IMPORTANT SAFETY INFORMATION ABOUT TASIGNA® (nilotinib) Capsules

QTc Prolongation and Sudden Death: TASIGNA® (nilotinib) capsules can cause QTc prolongation, a possibly life-threatening heart problem. QTc prolongation causes an irregular heartbeat, which may lead to sudden death. Call your doctor right away if you feel lightheaded, faint, or have an irregular heartbeat while taking TASIGNA. These can be symptoms of QTc prolongation.

- Your doctor should check your heart with a test called an electrocardiogram (ECG)
- Do not take TASIGNA if you have long QTc syndrome or low levels of potassium or magnesium in your blood
- TASIGNA can interact with many medicines and supplements. This may increase your chances for serious and life-threatening side effects. Do not take any other medicine while taking TASIGNA unless your doctor tells you it is okay to do so

IMPORTANT SAFETY INFORMATION ABOUT TASIGNA® (nilotinib) Capsules (CONTINUED)

- **Decreased Blood Flow to the Legs, Heart, or Brain:** People who have recently been diagnosed with Ph+ CML and take TASIGNA® (nilotinib) capsules may develop decreased blood flow to the legs, heart, or brain. Get medical help right away if you suddenly develop any of the following symptoms:
 - Chest pain or discomfort
 - Numbness or weakness
 - Problems walking or speaking
 - Leg pain or your leg feels cold
 - Change in the skin color of your leg
- **Pancreas Inflammation (Pancreatitis):** Call your doctor if you have symptoms including sudden stomach area pain with nausea and vomiting
- **Liver Problems:** TASIGNA can increase your risk of liver problems. People who have had liver problems in the past may be at risk for getting liver problems with TASIGNA. Call your doctor, or get medical help right away if you develop any symptoms of liver problems including stomach area (abdominal) pain, yellow skin/eyes, and dark-colored urine
- **Tumor Lysis Syndrome (TLS):** TLS is caused by a fast breakdown of cancer cells. Your doctor may do blood tests to check you for TLS. TLS can cause you to have kidney failure (with the need for dialysis treatment) and/or an abnormal heartbeat
- **Bleeding Problems:** Serious bleeding problems and death have happened during treatment with TASIGNA. Call your doctor right away if you develop signs and symptoms of bleeding such as uncontrolled bleeding, changes in eyesight, unconsciousness, sudden headache, or sudden confusion about your surroundings
- **Total Gastrectomy:** Tell your doctor if you have had a surgical procedure involving the removal of the entire stomach (total gastrectomy). Your doctor may need to change your dose
- **Lactose:** Tell your doctor if you have a severe problem with lactose (milk sugar) or other sugars. TASIGNA capsules contain lactose. Most people who have mild or moderate lactose intolerance can take TASIGNA
- **Fluid Retention:** Your body may hold too much fluid (fluid retention). Symptoms of fluid retention include shortness of breath, rapid weight gain, and swelling
- **Abnormal Growth or Development in Children:** Effects on growth and development have happened in children with chronic phase Ph+ CML during treatment with TASIGNA. Some children and adolescents who take TASIGNA may have slower than normal growth
- **Pregnancy and Breastfeeding:** TASIGNA should not be used during pregnancy since it may harm an unborn baby. If you become pregnant, think you may be pregnant, or are planning to become pregnant, tell your doctor right away. If you are able to become pregnant, your doctor should perform a pregnancy test before you start TASIGNA. Effective birth control should be used during treatment and for at least 14 days after your last TASIGNA dose. Do not breastfeed during treatment with TASIGNA and for at least 14 days after the final dose
- **Treatment-Free Remission in Adults:** Your doctor will monitor your CML during treatment with TASIGNA to see if you are in remission. After at least 3 years of treatment with TASIGNA, your doctor may do certain tests to determine if you continue to be in remission. Based on your test results, your doctor will decide if you are eligible to try stopping treatment with TASIGNA. This is called treatment-free remission (TFR)
 - Your doctor will carefully monitor your CML during and after you stop taking TASIGNA. If your test results show your CML is no longer in remission, your doctor will restart TASIGNA treatment

Please see Important Safety Information, including the **Boxed WARNING** throughout.



IMPORTANT SAFETY INFORMATION ABOUT TASIGNA® (nilotinib) Capsules (CONTINUED)

- It is important that your doctor does frequent monitoring to find out if you need to restart your TASIGNA® (nilotinib) capsules treatment. Follow your doctor's instructions about restarting TASIGNA if you are no longer in TFR
- **Drug Interactions:** TASIGNA can interact with many medicines and supplements. This may increase your chances for serious and life-threatening side effects. Tell your doctor about all the medicines you take including prescription and over-the-counter medicines, vitamins, and herbal supplements

If you need to take antacids (medicines to treat heartburn) do not take them at the same time that you take TASIGNA. If you take:

- A medicine to block the amount of acid produced in the stomach (H2 blocker): Take these medicines about 10 hours before you take TASIGNA or about 2 hours after you take TASIGNA
 - An antacid that contains aluminum hydroxide, magnesium hydroxide, and simethicone to reduce the amount of acid in the stomach: Take these medicines about 2 hours before or about 2 hours after you take TASIGNA
- **Common Side Effects in Adults and Children Include:**
 - Nausea
 - Diarrhea
 - Rash
 - Cough
 - Headache
 - Constipation
 - Tiredness
 - Muscle and joint pain
 - Itching
 - Vomiting
 - Fever
 - Night sweats
 - Runny or stuffy nose, sneezing, sore throat
 - **Side Effects in Adults Attempting TFR:** If you and your doctor decide that you can stop taking TASIGNA and try TFR, you may have more muscle and bone (musculoskeletal) symptoms than before you stopped treatment. Symptoms may include muscle pain, bone pain, arm and leg pain, spinal pain, and joint pain

Tell your doctor if you have any side effect that bothers you or does not go away. These are not all of the possible side effects of TASIGNA. For more information, ask your doctor or pharmacist.

You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

[Click here](#) for Full Prescribing Information including the **Boxed WARNING** and Medication Guide.

