

# DOCTOR DISCUSSION GUIDE FOR TASIGNA

## Newly diagnosed with Ph+ CML in chronic phase? Here's how to talk with your doctor about TASIGNA.

When you're diagnosed with Philadelphia chromosome–positive chronic myeloid leukemia in chronic phase (known as Ph+ CML-CP), it can be difficult to know where to start.

Luckily, we have tools to help. If you want more information, you can go to [www.TASIGNA.com](http://www.TASIGNA.com) to learn about signs, symptoms, and treatment milestones.

When you're ready to talk with your doctor, consider TASIGNA® (nilotinib) capsules as a treatment option. TASIGNA has been studied among newly diagnosed patients with Ph+ CML in chronic phase for 10 years.



### Here are some questions you can ask your doctor about TASIGNA.

When you go to your next appointment, print or save a digital copy of this list to help guide your conversation.

#### Is TASIGNA right for me?

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#### Approved Use:

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

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

**QTc Prolongation and Sudden Death:** TASIGNA 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.

Please see Important Safety Information, including the **Boxed WARNING** throughout and [click here](#) for full Prescribing Information, including **Boxed WARNING** and Medication Guide.



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**What tools, resources, and support programs are available for patients with Ph+ CML-CP?**

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**How long will I have to take TASIGNA® (nilotinib) capsules?**

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

**QTc Prolongation and Sudden Death:** TASIGNA 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
- Food and grapefruit products increase the amount of TASIGNA in your body. This may increase your chances for serious and life-threatening side effects. Take TASIGNA on an empty stomach
  - Avoid eating food for at least 2 hours before the dose is taken, and avoid eating food for at least 1 hour after the dose is taken
  - Avoid grapefruit, grapefruit juice, and any supplement containing grapefruit extract while taking TASIGNA

# DOCTOR DISCUSSION GUIDE FOR TASIGNA

**What are the potential side effects of TASIGNA® (nilotinib) capsules?**

**What should I do if I experience side effects while taking TASIGNA?**

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**When can I start taking TASIGNA?**

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**How will I know if TASIGNA is working?**

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## IMPORTANT SAFETY INFORMATION ABOUT TASIGNA® (nilotinib) Capsules (cont)

TASIGNA can cause serious side effects that can even lead to death. During treatment with TASIGNA your doctor will do tests to check for side effects. These tests will check your heart, blood cells (white blood cells, red blood cells, and platelets), electrolytes (potassium, magnesium), cholesterol, blood sugar, and pancreas and liver function. Your doctor may have you stop TASIGNA for some time or lower your dose if you have side effects. You should follow your doctor's instructions. Serious side effects include:

- **Low Blood Counts:** Low blood counts are common with TASIGNA but can also be severe. Your doctor will check your blood counts regularly during treatment with TASIGNA. Call your doctor right away if you have symptoms of low blood counts including:
  - Fever, chills, or other signs of infection
  - Unexplained bleeding or bruising
  - Shortness of breath
  - Unexplained weakness

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If you have any other questions or want to take note of important information during your appointment, use the space below:

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For even more tools and resources, go to

**[www.TASIGNA.com](http://www.TASIGNA.com)**

You'll find Ph+ CML-CP facts, guides on TASIGNA, real patient stories, and other helpful information.

## IMPORTANT SAFETY INFORMATION ABOUT TASIGNA® (nilotinib) Capsules (cont)

- **Decreased Blood Flow to the Legs, Heart, or Brain:** People who have recently been diagnosed with Ph+ CML and take TASIGNA 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

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## IMPORTANT SAFETY INFORMATION ABOUT TASIGNA® (nilotinib) Capsules (cont)

- **Liver Problems:** TASIGNA® (nilotinib) capsules 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
  - It is important that your doctor does frequent monitoring to find out if you need to restart your TASIGNA treatment. Follow your doctor's instructions about restarting TASIGNA if you are no longer in TFR

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## IMPORTANT SAFETY INFORMATION ABOUT TASIGNA® (nilotinib) Capsules (cont)

- **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](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

[Click here](#) for full Prescribing Information. Including the **Boxed WARNING**, and the TASIGNA Medication Guide.

