

TAKING  
TASIGNA,  
TESTING,  
AND  
TRACKING.

Patient portrayal

Please see Important Safety Information about TASIGNA® (nilotinib) capsules, including Boxed WARNING, throughout this brochure and Summary of Important Information on pages 38–42.

 **Tasigna**<sup>®</sup>  
(nilotinib) 150mg, 200mg capsules



# NOW THAT YOU'RE STARTING TREATMENT

# YOUR BLOOD DEMANDS TO BE HEARD.

## A guide to taking TASIGNA, monitoring your progress, and tracking your results

Your blood is counting on you more than ever. Your doctor has prescribed TASIGNA® (nilotinib) capsules to treat your Philadelphia chromosome–positive chronic myeloid leukemia (Ph+ CML). It's important to get started on treatment.

Most people with Ph+ CML are diagnosed in the first phase of the disease—called the chronic phase. The good news is that those in the chronic phase usually respond to treatment. That's why you'll want to work closely with your doctor to start on TASIGNA right away. If you have any questions, make sure your blood is heard by speaking with your doctor. You can also visit [www.tasigna.com](http://www.tasigna.com) to learn more.

### 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)

### 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

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SPEAK  
UP

AND  
SPEAK OUT  
FOR YOUR  
BLOOD.

This guide is designed to help you start on TASIGNA® (nilotinib) capsules and stay on track with your treatment. It walks you through what you need to know, from how to take TASIGNA to talking to your doctor about your progress. You'll also find:

- Tips on creating your own routine for taking TASIGNA as prescribed
- Information about possible side effects you may experience
- An overview of the blood tests your doctor may prescribe
- A tracker you can use to record the results of your blood tests
- A glossary of helpful terms

Having a productive conversation with your doctor about your treatment is exactly what your blood deserves. This guide can help make sure you are heard.

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

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.

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# TIMING YOUR MEDICATION

# AND YOUR MEALS.

Starting on any medication can take some getting used to. It's a good idea to create a routine that works with your schedule. In the following pages, you'll learn how to take TASIGNA® (nilotinib) capsules and find some practical tips to help make treatment part of what you do on a daily basis.



# HOW TO TAKE TASIGNA.

You'll want to set up your own schedule for taking TASIGNA® (nilotinib) capsules because the medication has to be taken at certain times and without food.

Your doctor will want you to take TASIGNA every day. You'll be prescribed either 150 mg or 200 mg capsules. Here are some key facts you need to know about taking TASIGNA.

**The usual dose of TASIGNA is 2 capsules in the morning and 2 in the evening**



**Take your doses of TASIGNA 12 hours apart, with water**

**Do NOT take TASIGNA with food**

One of the most important things to know about taking TASIGNA is that it should never be taken with food.

**Don't eat 2 hours before and 1 hour after you take TASIGNA**

You may drink water while you are not eating, before or after taking TASIGNA.



**Why you must take TASIGNA on an empty stomach**

Food may enhance your body's absorption of TASIGNA. If you take TASIGNA with food, it may increase the amount of TASIGNA in your blood in an unpredictable way, possibly to harmful levels. This can cause dangerous side effects such as irregular heart rhythm.

**If you cannot swallow capsules, try mixing TASIGNA in applesauce**

If you are unable to swallow TASIGNA capsules, the contents of each capsule may be mixed in 1 teaspoon of applesauce or apple purée, and swallowed right away (within 15 minutes).

**What if you miss a dose?**

It's important to take TASIGNA as prescribed, but if you should miss a dose, take your next dose as scheduled. Do not take a double dose to make up for a missed dose.

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

**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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# MAKING TASIGNA PART OF YOUR DAILY LIFE.

You'll want to set up a routine for taking TASIGNA® (nilotinib) capsules that works for your schedule. For example, you may prefer to take TASIGNA as soon as you wake up, and then wait at least an hour to eat breakfast. Then you will have 12 hours before you need to take your second dose of the day.

## Food and medication considerations

Do not eat grapefruit, drink grapefruit juice, or take supplements containing grapefruit extracts while on TASIGNA. This can raise the levels of TASIGNA in your body in an unpredictable manner.



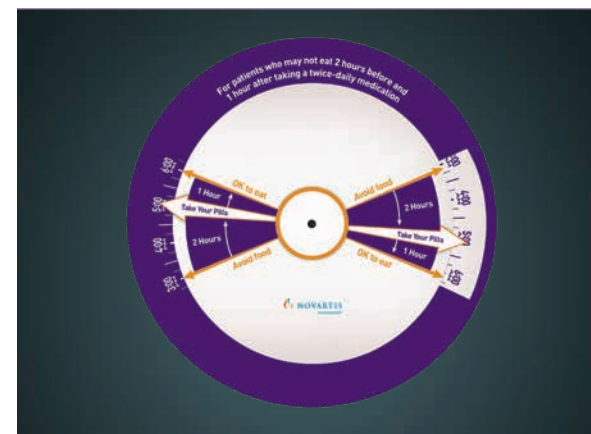
Certain medications may interact with TASIGNA in harmful ways. Before taking TASIGNA, tell your doctor if you are taking any other medicines. This includes medicines prescribed by other doctors you have seen, as well as medicines, herbs, and supplements that you buy without a prescription from a pharmacy, supermarket, or health food store.

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

## Use your phone to set up reminders to take TASIGNA

To help you keep track of when it's time to take TASIGNA, set up daily reminders on your phone. You may also want to use reminders for the times when you cannot eat before taking TASIGNA, and when it's okay to do so after you've taken the medication.



## Use the dosing wheel to help create your routine

In the TASIGNA Starter Kit you may have received from your doctor, you'll find a dosing wheel in the pocket of one of the brochures. The dosing wheel can help you see when to take your morning and evening doses of TASIGNA. Choose a time in the morning and the wheel will display the time for your evening dose. It also shows you the times you shouldn't eat before taking TASIGNA—and when you can eat.

## 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 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

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DON'T  
KEEP  
QUIET.

TALK  
TO YOUR  
DOCTOR  
ABOUT ANY  
SIDE  
EFFECTS.

As with any medication, it's important to discuss side effects you may experience with your doctor. This section reviews possible common and serious side effects of TASIGNA® (nilotinib) capsules. It also provides some tips to manage side effects that you may find helpful.



Patient portrayal

# UNDERSTANDING SIDE EFFECTS.

TASIGNA® (nilotinib) capsules may cause side effects in some patients.

Some of these side effects may be serious.

Be sure to tell your doctor about any side effects you are experiencing.

## The most common side effects of TASIGNA 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

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

- **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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Patient portrayal

# TIPS FOR MANAGING SIDE EFFECTS.

Side effects may vary among those taking TASIGNA® (nilotinib) capsules. It's important to speak with your doctor about any side effects you may experience.

Here are a few things to keep in mind:

- **Don't keep side effects to yourself:** Your doctor can only offer you tips to help you manage side effects if you make your doctor aware of them
- **Talk to your doctor before making any changes:** You may read something online about managing side effects, or get a tip from someone else with Ph+ CML. Be sure to speak with your doctor before making any changes to your daily routine
- **Keep track of any side effects:** You may find it helpful to write down any side effects you have. Be sure to make a note of the date and time you experienced a side effect

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

- **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

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# MONITORING YOUR BLOOD.

# TRACKING YOUR RESULTS.

Going for lab tests is a key part of your treatment plan when you have Ph+ CML. Because you and your doctor can only see how you're responding to TASIGNA® (nilotinib) capsules by looking at the results of regular blood tests.

In this section, you'll get an understanding of what your results mean and you'll have a place to record information about each of your blood tests.

