

# 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**  
(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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Patient portrayal

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.





# 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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# 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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Patient portrayal

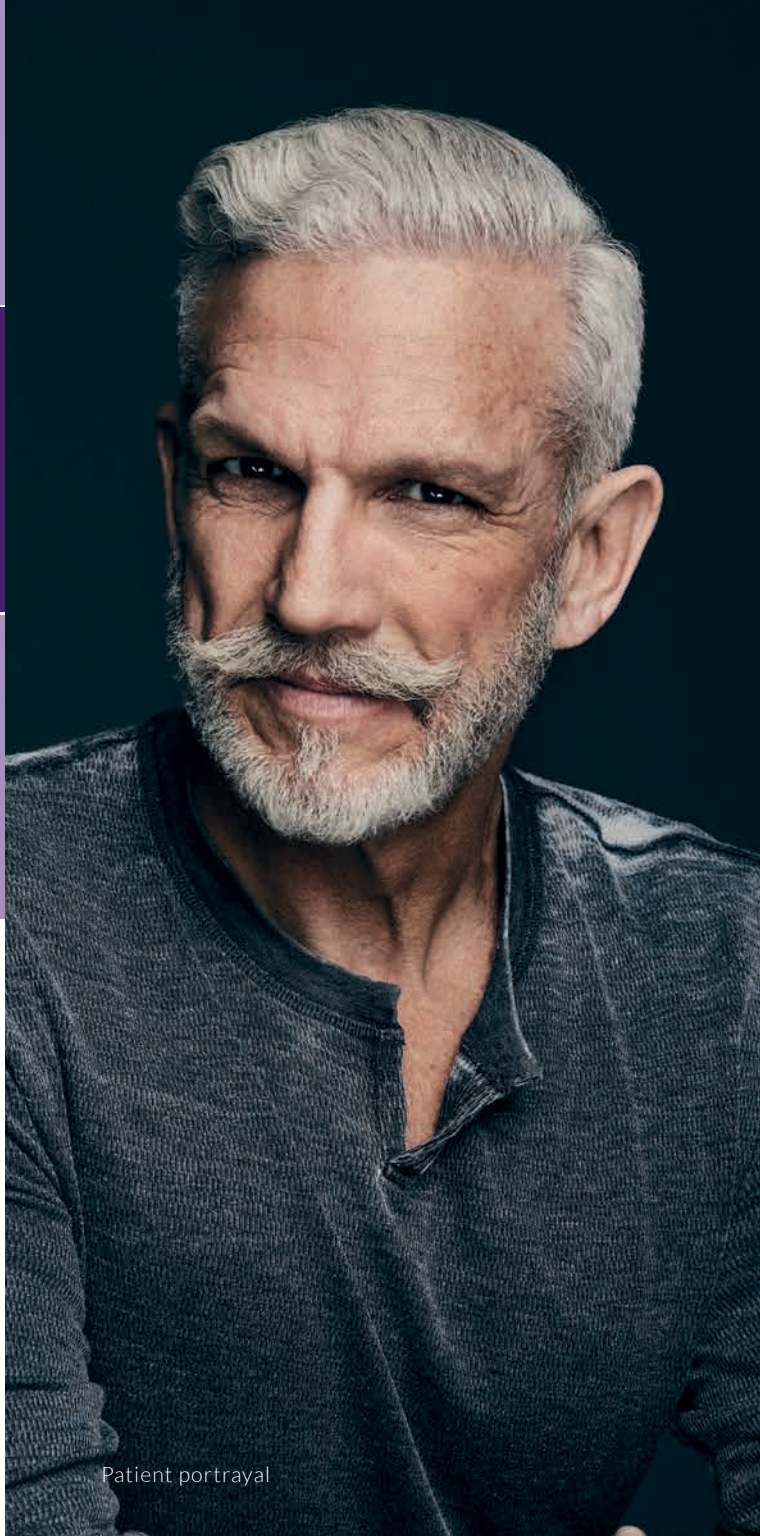
# MONITORING YOUR BLOOD.

# 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.





Patient portrayal

# YOUR BLOOD DEMANDS TO BE MONITORED.

### Regular blood tests can help you and your doctor see your progress

Monitoring matters when you're dealing with Ph+ CML. Your doctor may recommend tests of your blood and bone marrow every 3 months to see how TASIGNA® (nilotinib) capsules are working for you. It's important for you to go for any bloodwork your doctor prescribes—and to ask about your results.

### Measuring response to your treatment

When you're taking TASIGNA, you want to see the number of leukemic cells in your body go down. In addition to going for any bloodwork your doctor may require, it's important to talk with your doctor about what your results mean.

Here are the tests your doctor will likely recommend:

- **Complete blood count:** Counts the number of white blood cells, red blood cells, and platelets in the blood
- **Cytogenetic test:** Bone marrow is removed and your doctor measures the number of cells with the Philadelphia chromosome
- **Standardized polymerase chain reaction (PCR or molecular) test:** When the number of chronic myeloid leukemia (CML) cells is low, Philadelphia chromosome-positive (Ph+) cells may not be visible with a cytogenetic test. Only PCR testing is sensitive and clear enough to check for even the smallest amount of leukemic cells

### Testing, talking, tracking

Of course, it's not enough to get your blood tested. You need to discuss your results with your doctor, so you can track and understand your progress. To keep up with your bloodwork, use the following pages to record any tests your doctor may require—and your results.

### Other tests your doctor will conduct

During treatment with TASIGNA your doctor will do tests to check for side effects. These tests will check your heart (electrocardiogram), blood cells (white blood cells, red blood cells, and platelets), electrolytes (potassium, magnesium), cholesterol, blood sugar, pancreas function 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.

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

### ■ Common Side Effects in Adults and Children Include:

- |                                       |                                                                      |
|---------------------------------------|----------------------------------------------------------------------|
| <input type="checkbox"/> Nausea       | <input type="checkbox"/> Muscle and joint pain                       |
| <input type="checkbox"/> Diarrhea     | <input type="checkbox"/> Itching                                     |
| <input type="checkbox"/> Rash         | <input type="checkbox"/> Vomiting                                    |
| <input type="checkbox"/> Cough        | <input type="checkbox"/> Fever                                       |
| <input type="checkbox"/> Headache     | <input type="checkbox"/> Night sweats                                |
| <input type="checkbox"/> Constipation | <input type="checkbox"/> Runny or stuffy nose, sneezing, sore throat |
| <input type="checkbox"/> Tiredness    |                                                                      |

- **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

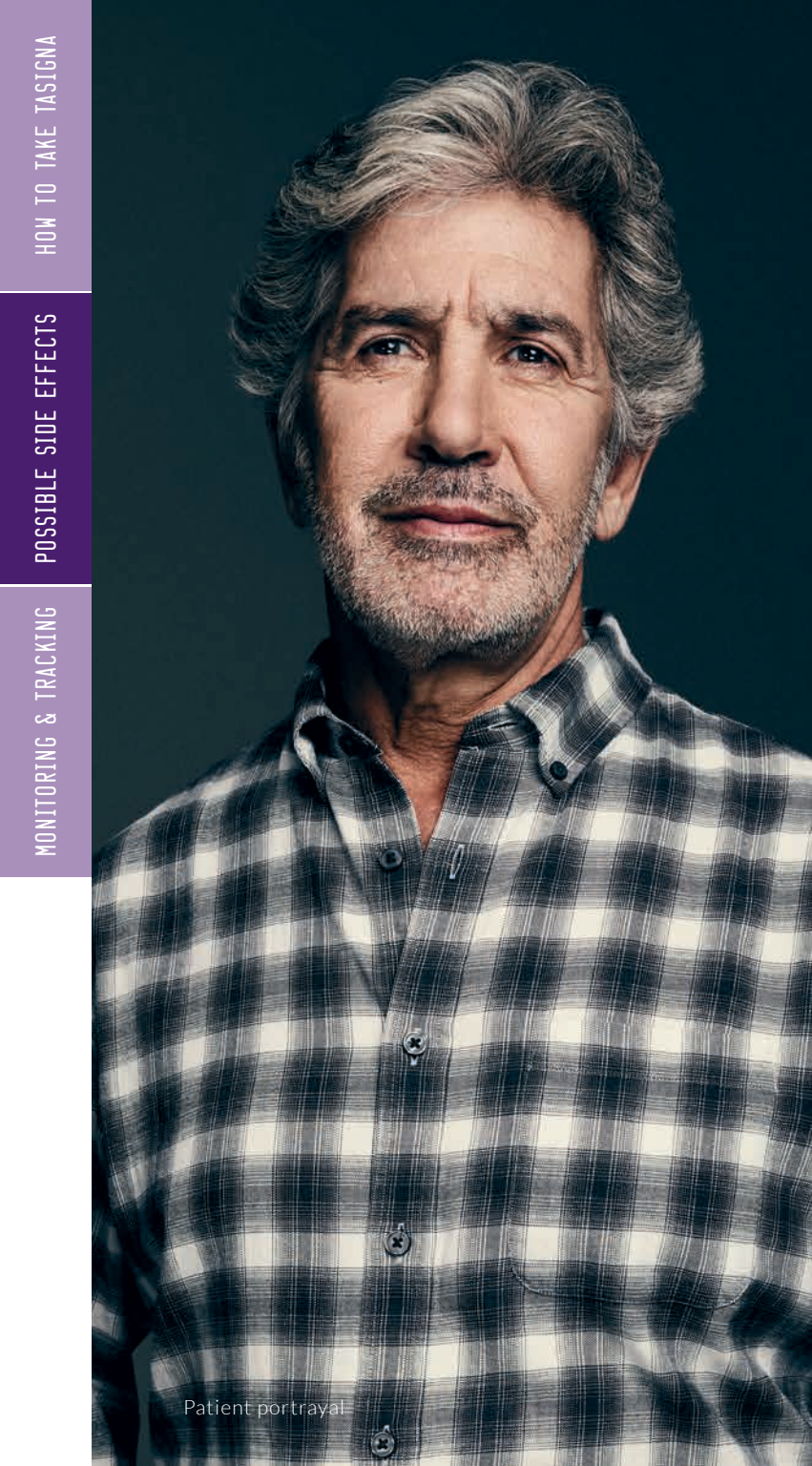
Tell your doctor if you have any side effect that bothers you or does not go away. These are not all of the possible side effects of TASIGNA. For more information, ask your doctor or pharmacist.

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.

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# TRACKING YOUR BLOOD TESTS.

## Help take the mystery out of your results

Understanding the results of your blood tests can help you have a productive conversation with your doctor about how you are responding to treatment. Here is some information about the tests your doctor is likely to order. You'll find the types of responses you may achieve and learn what to ask your doctor.

Use the following pages to record and track the results of your lab tests.

### Complete Blood Count (CBC) Test

#### Types of responses

- **Blood counts:** Determines if the number of white blood cells, red blood cells, and platelets are within the normal range

**Ask your doctor about:** Your CBC results and record your levels.

### Cytogenetic Test

#### Types of responses

- **Minor cytogenetic response:** More than 35% of cells in the bone marrow are Philadelphia chromosome-positive (Ph+)
- **Partial cytogenetic response (PCyR):** 1% to 35% of cells in the bone marrow are Ph+
- **Complete cytogenetic response (CCyR):** The number of cells in the bone marrow with Ph+ is undetectable

**Ask your doctor about:** Your cytogenetic results and record the percentage of Ph+ cells detected.

### Standardized Polymerase Chain Reaction (PCR or molecular) Test

The PCR test measures the number of cells that have the *BCR-ABL1* gene. This abnormal gene creates a damaged protein called BCR-ABL. It causes the bone marrow to create leukemic cells.

#### Types of responses

- **Early molecular response:** The amount of the *BCR-ABL1* gene in the body is less than or equal to ( $\leq$ )10% at 3 months and 6 months after starting treatment. This means that no more than 10 out of every 100 cells has the *BCR-ABL1* gene
- **Major molecular response (MMR):** The amount of *BCR-ABL1* in the body is  $\leq$ 0.1%. This means that 1 out of every 1000 cells has the *BCR-ABL1* gene
- **Deep molecular response (DMR):** The amount of *BCR-ABL1* in the body is almost undetectable. Your doctor may call this MR4.5 (*BCR-ABL1*  $\leq$ 0.0032%). This means that 1 out of every 32,000 cells has the *BCR-ABL1* gene

**Ask your doctor about:** Your PCR test results and record the percentage of *BCR-ABL1* detected.

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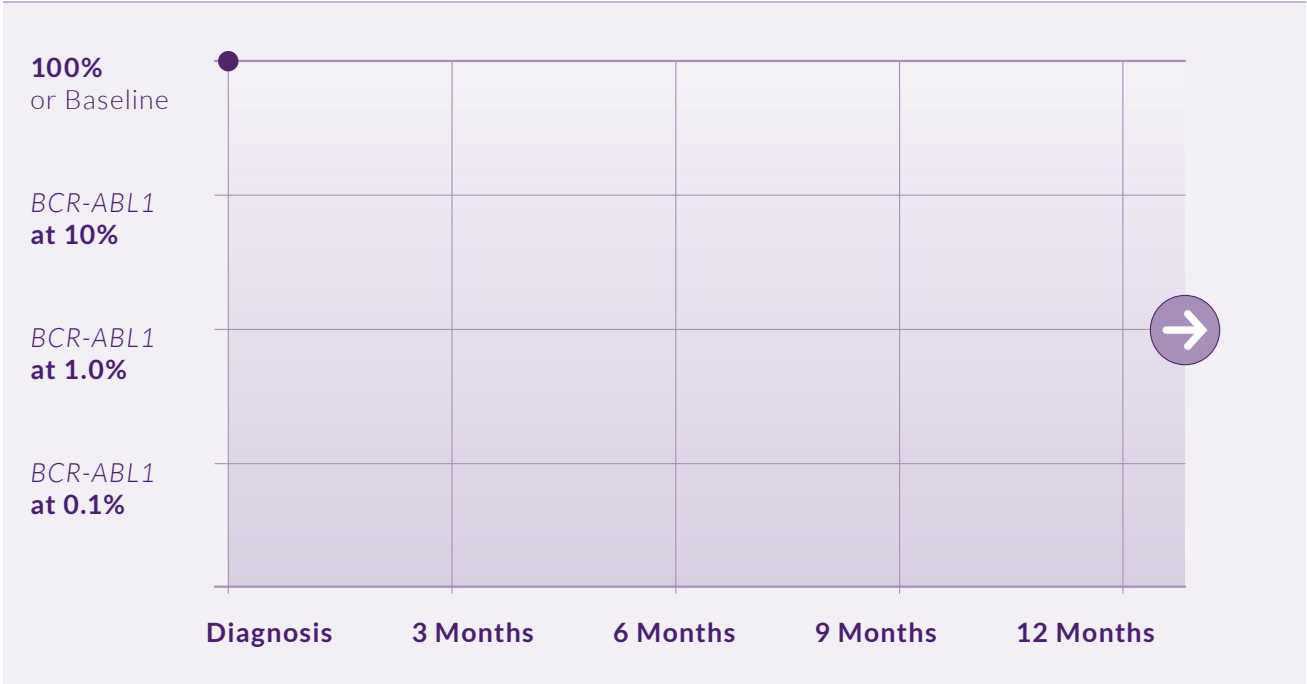


# TRACKING YOUR TEST RESULTS.

DATE	LAB TEST	RESULTS	CHANGE FROM LAST TEST	NEXT TEST
5/1	S Cytogenetic A	BCR-ABL1 15% M	Down 15% L	PCR on 5/15 E

# SEE THE STATUS OF YOUR PCR TEST RESULTS FOR YOURSELF.

- Here’s how to use the graph below:
- The first entry for your baseline is already marked by the purple dot at the top of the chart—next to 100%
  - Record the percentage of *BCR-ABL1* detected after each PCR test, which your doctor may order every 3 months
  - Connect the dots as you add entries to see how you are tracking. Talk with your doctor if you have questions about how to use this graph



DATE	LAB TEST	RESULTS	CHANGE FROM LAST TEST	NEXT TEST

DATE	LAB TEST	RESULTS	CHANGE FROM LAST TEST	NEXT TEST



DATE	LAB TEST	RESULTS	CHANGE FROM LAST TEST	NEXT TEST

DATE	LAB TEST	RESULTS	CHANGE FROM LAST TEST	NEXT TEST



Patient portrayal

# MANAGING Ph+ CML

# STARTS WITH SUPPORT.

Ph+ CML may be considered a rare blood cancer, but that doesn't mean you have to go it alone. Learn about the support options available to you and the many organizations and groups who are here for you.







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# YOUR BLOOD DEMANDS SUPPORT.

Now that you're starting on TASIGNA® (nilotinib) capsules, you should know that you have access to resources to help you manage Ph+ CML, including:

- The TASIGNA On Demand Support Program
- The TASIGNA Patient Navigator Program

## Sign up for support from TASIGNA On Demand

### TASIGNA ON DEMAND SUPPORT PROGRAM

Now's the time to visit [www.tasigna.com](http://www.tasigna.com) to sign up for the TASIGNA On Demand patient support program. You'll receive helpful information via mail and email, including:

- Educational materials about Ph+ CML and TASIGNA
- Information about the importance of going for blood tests—and understanding what your results mean
- Background on treatment milestones to discuss with your doctor
- Tips to help you manage Ph+ CML
- Information about saving on TASIGNA

## Get one-on-one support from Patient Navigators

If you are just starting on TASIGNA, you can sign up for a more personalized level of support with the TASIGNA Patient Navigator Program.

One of our specially trained Patient Navigators will work with you to set up a convenient time for one-on-one phone calls—with a focus on your first 90 days of treatment. During your calls, your Patient Navigator can:

- Help you create a dosing routine that works for your schedule
- Answer questions that you may have about TASIGNA
- Explain the different kinds of blood tests your doctor may require
- Stay on top of any blood tests you may need

To enroll in the Patient Navigator Program, call **1-800-282-7630**.

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MEET  
OTHERS  
WHO ARE  
MAKING  
THEIR  
BLOOD  
HEARD.

Patient portrayal

Real people, real stories, real results

No one gets what you're going through like another person with Ph+ CML. You can watch videos of actual patients on TASIGNA® (nilotinib) capsules, who share their stories with you. Go to [www.tasigna.com](http://www.tasigna.com).

Follow TASIGNA on Facebook and Instagram

To keep up with the latest news about TASIGNA and Ph+ CML, follow us on Facebook and Instagram.



Connect with others who have Ph+ CML

Some of the more common forms of cancer get a lot of attention. Ph+ CML, on the other hand, is considered a rare cancer. That's all the more reason to reach out to people like you who are living with Ph+ CML. The organizations listed below may be a helpful source of connections, information, and support.

Leukemia & Lymphoma Society®

[www.LLS.org](http://www.LLS.org)  
1-800-955-4572

Leukemia Research Foundation

[www.allbloodcancers.org](http://www.allbloodcancers.org)  
1-847-424-0600

The National CML Society

[www.nationalcmlsociety.org](http://www.nationalcmlsociety.org)  
1-877-431-2573

American Cancer Society®

[www.cancer.org](http://www.cancer.org)  
1-800-ACS-2345 (1-800-227-2345)

The Max Foundation

[www.themaxfoundation.org](http://www.themaxfoundation.org)  
1-888-462-9368

National Cancer Institute's Cancer Information Service

[www.cancer.gov/aboutnic/cis](http://www.cancer.gov/aboutnic/cis)  
1-800-4CANCER (1-800-422-6237)  
Those with TTY equipment may call  
1-800-332-8615

CancerCare®

[www.cancercare.org](http://www.cancercare.org)  
1-800-813-HOPE (1-800-813-4673)

National Patient Advocate Foundation

[www.npaf.org](http://www.npaf.org)  
1-202-347-8009

The organizations and websites listed on this page are maintained by third parties over whom Novartis Pharmaceuticals Corporation has no control. As such, Novartis Pharmaceuticals Corporation makes no representation as to the accuracy or any other aspect of the information supplied by these organizations or contained in these websites.

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# TALKING ABOUT TESTING.

Ph+ CML has its own language when it comes to blood tests and results. Here is a glossary of terms your doctor may use in discussing your bloodwork and your progress.

**BCR-ABL1:** An abnormal gene that creates a damaged protein by the same name. It causes the bone marrow to create leukemic cells. The *BCR-ABL1* gene is formed when 2 specific chromosomes combine. The gene then creates the BCR-ABL protein—the underlying cause of Ph+ CML.

**Bone marrow:** A sponge-like tissue found in the center of most bones.

**Complete blood count (CBC) test:** Determines if the number of white blood cells, red blood cells, and platelets are within the normal range

**Complete cytogenetic response (CCyR):** The number of cells in the bone marrow with Ph+ is undetectable.

**Cytogenetic test:** Bone marrow is removed and your doctor measures the number of cells with the Philadelphia chromosome.

**Deep molecular response (DMR):** When the amount of *BCR-ABL1* in the body is almost undetectable. Your doctor may call this MR4.5 (*BCR-ABL1*  $\leq 0.0032\%$ ). This means that 1 out of every 32,000 cells has the *BCR-ABL1* gene.

**Early molecular response:** The amount of the *BCR-ABL1* gene in the body is less than or equal to ( $\leq$ )10% at 3 months and 6 months after starting treatment. This means that no more than 10 out of every 100 cells has the *BCR-ABL1* gene.

**Major molecular response (MMR):** The amount of *BCR-ABL1* in the body is low, specifically *BCR-ABL1*  $\leq 0.1\%$ . This means that 1 out of every 1000 cells has the *BCR-ABL1* gene.

**Minor cytogenetic response:** More than 35% of cells in the bone marrow are Ph+ cells.

**Molecular response (MR):** Refers to a decrease in the number of cells in the blood with *BCR-ABL1*.

**Partial cytogenetic response (PCyR):** 1% to 35% of all the cells in the bone marrow have the Philadelphia chromosome.

**Polymerase chain reaction (PCR or molecular) test:** When the number of chronic myeloid leukemia (CML) cells is low, Philadelphia chromosome–positive (Ph+) cells may not be visible with a cytogenetic test. Only PCR testing is sensitive and clear enough to check for even the smallest amount of leukemic cells.

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# SUMMARY OF IMPORTANT INFORMATION FOR TASIGNA® (NILEOTINIB) CAPSULES.

## What is TASIGNA?

TASIGNA is a prescription medicine used to treat:

- adults and children who have been newly diagnosed with a certain type of leukemia called Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase.
- adults with chronic phase Ph+ CML or accelerated phase Ph+ CML who:
  - are no longer benefiting from other treatments, including imatinib (GLEEVEC), **or**
  - have taken other treatments, including imatinib (GLEEVEC), and cannot tolerate them.

## What is the most important information I should know about TASIGNA?

**TASIGNA can cause a possible life-threatening heart problem called QTc prolongation.** QTc prolongation causes an irregular heartbeat, which may lead to sudden death.

**Your healthcare provider should check the electrical activity of your heart with a test called an electrocardiogram (ECG):**

- before starting TASIGNA
- 7 days after starting TASIGNA
- with any dose changes
- regularly during TASIGNA treatment

**You may lower your chances for having QTc prolongation with TASIGNA if you:**

- **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 during treatment with TASIGNA. Food and grapefruit products increase the amount of TASIGNA in your body.
- Avoid taking other medicines or supplements with TASIGNA that can also cause QTc prolongation.
- TASIGNA can interact with many medicines and supplements and increase your chance for serious and life-threatening side effects
- Do not take any other medicine during treatment with TASIGNA unless your healthcare provider tells you it is okay to do so.

- If you cannot swallow TASIGNA capsules whole, you may open the TASIGNA capsule and sprinkle the contents of each capsule in 1 teaspoon of applesauce (puréed apple). Swallow the mixture right away (within 15 minutes). For more information, see "How should I take TASIGNA?"

**Call your healthcare provider right away if you feel lightheaded, faint, or have an irregular heartbeat during treatment with TASIGNA. These can be symptoms of QTc prolongation.**

## Who should not take TASIGNA?

Do not take if you have:

- low levels of potassium or magnesium in your blood
- long QTc syndrome

**Before taking TASIGNA, tell your healthcare provider about all of your medical conditions, including if you:**

- have heart problems
- have had a stroke or other problems due to decreased blood flow to the brain
- have problems with decreased blood flow to your legs
- have irregular heartbeat
- have QTc prolongation or a family history of it
- have liver problems
- have had pancreatitis
- have low blood levels of potassium or magnesium in your blood
- 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.

- have bleeding problems
- had a surgical procedure involving the removal of the entire stomach (total gastrectomy)
- are pregnant or plan to become pregnant. TASIGNA can harm your unborn baby. Tell your healthcare provider right away if you are pregnant, or if you become pregnant during treatment with TASIGNA.

## In females who are able to become pregnant:

- Your healthcare provider should do a pregnancy test before you start treatment with TASIGNA.
- Use effective birth control (contraception) during treatment with TASIGNA for at least 14 days after the last dose.
- Are breastfeeding or plan to breastfeed. It is not known if TASIGNA passes into your breast milk. Do not breastfeed during treatment and for at least 14 days after your last dose of TASIGNA.

**Tell your healthcare provider 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.

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





SUMMARY OF IMPORTANT INFORMATION FOR TASIGNA® (nilotinib) Capsules (continued)

TASIGNA can interact with many medicines and supplements and increase your chance for serious and life-threatening side effects. **See “What is the most important information I should know about TASIGNA?”**

How should I take TASIGNA?

- Take TASIGNA exactly as your healthcare provider tells you to take it.
- Do not change your dose or stop taking TASIGNA unless your healthcare provider tells you.
- TASIGNA is a long-term treatment.
- Your healthcare provider will tell you how many TASIGNA capsules to take and when to take them.
- If your child takes TASIGNA, your healthcare provider will change the dose as your child grows.
- **TASIGNA must be taken 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.**
- Swallow TASIGNA capsules whole with water. If you cannot swallow TASIGNA capsules whole, tell your healthcare provider.
- **If you cannot swallow TASIGNA capsules whole:**
  - **Open the TASIGNA capsules and sprinkle the contents in 1 teaspoon of applesauce (puréed apple).**
    - **Do not use more than 1 teaspoon of applesauce.**

- **Only use applesauce. Do not sprinkle TASIGNA onto other foods.**
  - **Swallow the mixture right away (within 15 minutes).**
- Do not drink grapefruit juice, eat grapefruit, or take supplements containing grapefruit extract at any time during treatment. **See “What is the most important information I should know about TASIGNA?”**
- If you miss a dose, just take your next dose at your regular time. Do not take 2 doses at the same time to make up for a missed dose.
- If you take too much TASIGNA, call your healthcare provider or go to the nearest hospital emergency room right away. Symptoms may include vomiting and drowsiness.
- During treatment with TASIGNA your healthcare provider will do tests to check for side effects and to see how well TASIGNA is working for you. The tests will check your:
  - heart
  - blood cells (white blood cells, red blood cells, and platelets). Your blood cells should be checked every 2 weeks for the first 2 months and then monthly.
  - electrolytes (potassium, magnesium)
  - pancreas and liver function
  - bone marrow samples

Your healthcare provider may change your dose. Your healthcare provider may have you stop TASIGNA for some time or lower your dose if you have side effects with it.

- Your healthcare provider will monitor your CML during treatment with TASIGNA to see if you are in a remission. After at least 3 years of treatment with TASIGNA, your healthcare provider may do certain tests to determine if you continue to be in remission. Based on your test results, your healthcare provider may decide if you may be eligible to try stopping treatment with TASIGNA. This is called Treatment Free Remission (TFR).
- Your healthcare provider will carefully monitor your CML during and after you stop taking TASIGNA. Based on your test results, your healthcare provider may need to re-start your TASIGNA if your CML is no longer in remission.
- It is important that you are followed by your healthcare provider and undergo frequent monitoring to find out if you need to re-start your TASIGNA treatment because you are no longer in TFR. Follow your healthcare provider’s instructions about re-starting TASIGNA if you are no longer in TFR.

What are the possible side effects of TASIGNA?  
TASIGNA may cause serious side effects, including:

- **See “What is the most important information I should know about TASIGNA?”**
- **Low blood cell counts.** Low blood cell counts (red blood cells, white blood cells, and platelets) are common with TASIGNA, but can also be severe. Your healthcare provider will check your blood counts regularly during treatment with TASIGNA. Call your healthcare provider or get medical help right away if you develop any signs or symptoms of low blood counts including:
  - fever
  - chills or other signs of infection
  - unexplained bleeding or bruising
  - unexplained weakness

- shortness of breath
- **Decreased blood flow to the leg, heart, or brain.** People who have recently been diagnosed with Ph+ CML and take TASIGNA may develop decreased blood flow to the leg, the 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
  - your leg feels cold
  - change in the skin color of your leg
- **Pancreas inflammation (pancreatitis).** Tell your healthcare provider right away if you develop any symptoms of pancreatitis 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 healthcare provider or get medical help right away if you develop any symptoms of liver problems including:
  - stomach area (abdominal) pain
  - yellow skin and eyes
  - dark-colored urine
- **Tumor Lysis Syndrome (TLS).** TLS is caused by a fast breakdown of cancer cells. Your healthcare provider may do blood tests to check you for TLS. TLS can cause you to have:
  - **kidney failure and the need for dialysis treatment**
  - **an abnormal heart beat**





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

To learn more about Ph+ CML and TASIGNA, visit [\*\*www.tasigna.com\*\*](http://www.tasigna.com).

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