STARTING ON TASIGNA
Your guide to learning about Ph+ CML and TASIGNA® (nilotinib)

Please see Important Safety Information including Boxed WARNING on pages 44-47. Please click here for full Prescribing Information, and the TASIGNA® (nilotinib) Medication Guide. All patients featured in this brochure are taking TASIGNA for Ph+ CML and were compensated by Novartis.
WELCOME TO TASIGNA

By choosing TASIGNA® (nilotinib), you and your doctor have made an important step in treating your Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML).

Whether you're a newly diagnosed patient, or changing from another treatment, this brochure will help you start treatment with TASIGNA. Use this brochure to learn more about your condition, your treatment, and the support resources available to help you manage Ph+ CML.

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TASIGNA® (nilotinib) Indications

TASIGNA is a prescription medicine used to treat adults who have:

- Newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase. The effectiveness of TASIGNA in these patients is based on a study that measured two types of response to treatment (cytogenetic and molecular).
- Ph+ CML in chronic phase and accelerated phase who are no longer benefiting from, or did not tolerate, other treatment including GLEEVEC® (imatinib mesylate). The effectiveness of TASIGNA in these patients is based on a study that measured two types of response to treatment (hematologic and cytogenetic).

IMPORTANT SAFETY INFORMATION ABOUT TASIGNA® (nilotinib) Capsules

What is the most important information to know about prescription TASIGNA?

- TASIGNA can cause QT prolongation, a possible life-threatening heart problem. QT prolongation causes an irregular heartbeat, which may lead to sudden death. Call your doctor if you feel lightheaded, faint or have an irregular heartbeat while taking TASIGNA. These can be symptoms of QT prolongation.
- Your doctor should check 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

- 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 chance 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 chance 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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What is Ph+ CML?

Philadelphia chromosome-positive myeloid leukemia (Ph+ CML) is a type of cancer affecting the blood and bone marrow. In people with Ph+ CML, the bone marrow produces too many white blood cells and these cells are often immature or damaged.

In Ph+ CML, your bone marrow cells have an abnormal chromosome that causes your body to produce too many white blood cells. These white blood cells crowd out normal, healthy cells and are often damaged.

Normal blood cells vs. Blood cells in person with Ph+ CML

- **Normal blood cells**
  - Red blood cell - carries oxygen from the lungs to the rest of the body
  - White blood cell - helps your body fight infection and disease
  - Platelet - a clear, disk-shaped piece of a cell that forms blood clots

- **Blood cells in person with Ph+ CML**
  - Red blood cell - carries oxygen from the lungs to the rest of the body
  - Leukemic cell - diseased white blood cell that grows abnormally
  - White blood cell - helps your body fight infection and disease

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What causes Ph+ CML?

This series of images shows the creation of the Philadelphia chromosome and the BCR-ABL gene, the genetic culprits in Ph+ CML.

Ph+ CML happens when genetic material from one chromosome switches position with genetic material from another chromosome. Humans have 46 chromosomes and chromosomes are made up of genes. Genes are part of your DNA, and are found within all your cells. Genes contain instructions for making proteins that are used throughout the body. Damaged genes may create faulty proteins, which may cause harm.

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In Ph+ CML, pieces of chromosomes 9 and 22 have broken off and switched places.

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This creates a new abnormal chromosome called the Philadelphia chromosome (Ph) which contains a gene called BCR-ABL.

The BCR-ABL gene creates a faulty protein, also called BCR-ABL. The faulty BCR-ABL protein made in CML is like a broken switch—signaling immature white blood (leukemia) cells to multiply. These cells are often damaged and crowd out healthy cells.
The phases of Ph+ CML

The phases of Ph+ CML are based on the percentage of blast cells (immature white blood cells) as compared with other blood cells in the bone marrow. Most adults with Ph+ CML are diagnosed in the chronic phase, which is the initial phase of the disease.

**CHRONIC PHASE**

- <10% of blood cells in the bone marrow samples are blast cells*

**ACCELERATED PHASE**

- 10-19% of blood cells in the bone marrow samples are blast cells*

**BLAST CRISIS**

- ≥20% of blood cells in the bone marrow samples are blast cells*

*Based on World Health Organization (WHO) criteria

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**Navigating Ph+ CML**

A hands-on guide through the phases of CML

To help you better understand your condition, we’ve created Navigating Ph+ CML, a comprehensive educational and interactive video experience where you can:

- Learn valuable information about Ph+ CML
- Hear the personal story of basketball legend Kareem Abdul-Jabbar, who is taking TASIGNA® (nilotinib) for his Ph+ CML in the chronic phase
- Watch Ph+ CML experts and get useful information about the condition, including nutrition and lifestyle tips

Get started now at www.TASIGNA.com/resources.

*Based on World Health Organization (WHO) criteria

Kareem Abdul-Jabbar is a patient taking TASIGNA and is compensated by Novartis. The other individuals are healthcare professionals that are compensated by Novartis.
Importance of testing

Periodic molecular testing is an important part of treatment. Your doctor may recommend molecular testing every 3 months to see if you’re reaching your treatment milestones, and decide if changes to your Ph+ CML therapy are needed.

Track your progress

Use the Tracking Journal found in this kit to track your test results over time. Be sure to talk with your doctor or nurses about your results, or any questions you may have, so you fully understand how you’re doing with your treatment.

Get free PCR tests

Novartis is committed to achieving the highest standard of Ph+ CML care. That’s why we’re offering free PCR testing for eligible patients. Talk to your doctor or nurse to find a lab that is participating in the Get IS RQ-PCR NOW program.

*Please note that non-US residents, patients covered under Medicare, Medicaid, or a similar state or federal program, and residents of Massachusetts and Michigan are not eligible for the Get IS RQ-PCR NOW program. Novartis reserves the right to rescind, revoke, or amend this program without notice.

Types of tests

**HEMATOLOGIC TESTS**

This is a simple blood test that counts the number of white blood cells, red blood cells, and platelets in your blood.

- If your blood cell counts have returned to within the normal range, you have achieved what is called a complete hematologic response (CHR).
- You may sometimes see this referred to as a CBC or complete blood count test.

**CYTOGENETIC TESTS**

In cytogenetic testing, laboratory technicians look at samples of your bone marrow under a microscope and count the number of cells that contain the Ph chromosome. This practice is called karyotyping. If no cells with the Ph chromosome are found, it is called a complete cytogenetic response (CCyR).

**MOLECULAR TESTS**

A PCR (polymerase chain reaction) test requires a sample of blood or bone marrow. It is the most sensitive kind of test available for monitoring response to Ph+ CML treatment. A PCR test can find 1 leukemic cell in at least 100,000 normal cells. Results may be standardized to the international scale (IS), so you may sometimes see this test referred to as IS-PCR.

- You may sometimes see this test referred to as IS-PCR or IS RQ-PCR (real-time quantitative polymerase chain reaction). Both are acceptable.
- The standardized results will let you know if you are meeting treatment milestones.

- A major molecular response (MMR) means that the amount of BCR-ABL found in the bone marrow sample or blood sample is very low. PCR testing can determine if you’ve achieved an MMR.

- In cytogenetic testing, laboratory technicians look at samples of your bone marrow under a microscope and count the number of cells that contain the Ph chromosome. This practice is called karyotyping. If no cells with the Ph chromosome are found, it is called a complete cytogenetic response (CCyR).

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- A major molecular response (MMR) means that the amount of BCR-ABL found in the bone marrow sample or blood sample is very low. PCR testing can determine if you’ve achieved an MMR.
Treatment milestones

Throughout your treatment, you may see the amount of leukemic cells in your body drop by levels of 10. This is called a log reduction. Periodic testing will let you and your doctor know whether you are reaching these milestones in the recommended timeframe.

- **At Diagnosis**: The levels of leukemia cells in your body will be checked when you’re first diagnosed. This level will be your baseline.
  
  To see if you’re responding to treatment, your doctor will compare each new level to your baseline.

- **1-log Reduction**: A log reduction means that the levels of leukemia cells are 10 times lower than the standardized baseline.
  
  This is also known as a major cytogenetic response (MCyR).

- **2-log Reduction**: A 2-log reduction means your levels are 100 times lower than the standardized baseline.
  
  This is also known as a complete cytogenetic response (CCyR).

- **3-log Reduction**: A 3-log reduction means your levels are 1000 times lower than when compared to the standardized baseline.
  
  This is also known as a major molecular response (MMR).

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What is TASIGNA?

TASIGNA® (nilotinib) is part of a class of therapies known as tyrosine-kinase inhibitors, or TKIs. TKIs are used to treat Ph+ CML. TASIGNA binds to a specific protein that is thought to cause the overproduction of white blood cells, the root cause of Ph+ CML.

TASIGNA is a prescription medicine used to treat adults who have newly diagnosed Ph+ CML in chronic phase or Ph+ CML in chronic phase and accelerated phase who are no longer benefiting from, or did not tolerate, other treatment including GLEEVEC® (imatinib mesylate).

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How TASIGNA works

TASIGNA® (nilotinib) is taken to help reduce the amount of leukemic cells in the body. The exact mechanism is unknown but this series of images shows how TASIGNA is thought to work.

1. Ph+ CML happens when an abnormal gene called Bcr-Abl produces an abnormal protein, also called BCR-ABL.

2. The BCR-ABL protein sends a signal that creates leukemic cells in the blood and bone marrow.

3. During in vitro studies, meaning studies that were conducted in test tubes, TASIGNA was shown to bind to and stabilize the inactive formation of the ABL protein. This blocked the signal that leads to the production of leukemic cells.

4. Blocking the signal may reduce the amount of leukemic cells and allow healthy blood cells to grow.

Important Safety Information

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Demonstrated response with TASIGNA

TASIGNA® (nilotinib) has been studied in more than 1,300 Ph+ CML patients over 7 years. TASIGNA has demonstrated response in both newly diagnosed patients, and patients who changed to TASIGNA after another drug (imatinib) did not work.

Important Safety Information

TASIGNA may cause serious side effects, including:

• Low blood counts: Low blood counts are common with TASIGNA. Your doctor will check your blood counts regularly during treatment with TASIGNA. Symptoms of low blood counts include:
  o Unexplained bleeding or bruising
  o Blood in urine or stool
  o Unexplained weakness

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Results for newly diagnosed patients

In a clinical trial of newly diagnosed patients taking either TASIGNA or GLEEVEC® (imatinib), TASIGNA was shown to be more effective based on several criteria:

- **Major Molecular Response (MMR)**
  - Twice as many patients who took TASIGNA achieved a major molecular response (MMR) one year into the clinical trial as patients who took imatinib.

- **Fewer Patients Progress to Accelerated Phase or Blast Crisis**
  - For 99% of patients who took TASIGNA, their Ph+ CML did not progress to the accelerated or blast crisis phase after 5 years, compared to 95% of imatinib patients.

Fewer Patients Progress to Accelerated Phase or Blast Crisis

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Major Molecular Response (MMR)

Twice as many patients who took TASIGNA achieved a major molecular response (MMR) one year into the clinical trial as patients who took imatinib.
Demonstrated response for patients changing to TASIGNA

In a clinical trial of patients who had taken GLEEVEC® (imatinib mesylate) before changing to TASIGNA, TASIGNA was shown to be effective:

Major Cytogenetic Response (MCyR)
51% of Ph+ CML patients in chronic phase achieved major cytogenetic response (MCyR). This means 0%-35% of the cells in the bone marrow test positive for the Philadelphia chromosome.

Hematologic response (HR)
Almost 40% of patients in accelerated phase achieved hematologic response (HR).

Demonstrated response with TASIGNA (Continued)

Important Safety Information
TASIGNA® (nilotinib) may cause serious side effects, including:
- 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:
  o Chest pain or discomfort
  o Numbness or weakness
  o Problems walking or speaking
  o Leg pain
  o Your leg feels cold
  o Change in the skin color of your leg

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To learn more about the clinical trial results for TASIGNA, be sure to talk to your doctor. You can also visit www.TASIGNA.com.
Understanding side effects

TASIGNA may cause side effects in some patients. Some of these side effects may be serious.

- Side effects may vary from patient to patient
- Write down any side effects you are experiencing and share this information with your doctor

IMPORTANT SAFETY INFORMATION ABOUT TASIGNA® (nilotinib) Capsules

What is the most important information to know about prescription TASIGNA?

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- Your doctor should check 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

- 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 chance 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. 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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Serious side effects:

Low blood counts
Low blood counts are common with TASIGNA. Your doctor will check your blood counts every 2 weeks for 2 months then monthly thereafter. Symptoms of low blood counts include:
- Unexplained bleeding or bruising
- Blood in urine or stool
- Unexplained weakness

QT prolongation
Call your doctor right away if you feel lightheaded, faint or have an irregular heartbeat while taking TASIGNA. These can be symptoms of QT prolongation, a possible life-threatening heart problem

Pancreas inflammation (pancreatitis)
Symptoms include sudden stomach area pain with nausea and vomiting

Fluid Retention
Your body may hold too much fluid (fluid retention). Symptoms of fluid retention include shortness of breath, rapid weight gain, and swelling

Tumor Lysis Syndrome (TLS)
TLS is caused by a fast breakdown of cancer cells. TLS can cause you to have:
- Kidney failure and the need for dialysis treatment
- An abnormal heart beat

Your doctor may do blood tests to check you for TLS.

Liver damage
Symptoms include yellow skin and eyes

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:
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Common side effects:
Most patients experience side effects at some time. Some common side effects you may experience include:

- Low blood count
- Nausea
- Rash
- Headache
- Tiredness

- Itching
- Vomiting
- Diarrhea
- Cough
- Constipation
- Muscle and joint pain
- Runny or stuffy nose, sneezing, sore throat
- Fever
- Night sweats

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® (nilotinib). 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.

Please see Important Safety Information including Boxed WARNING on pages 44-47. Please click here for full Prescribing Information, and the TASIGNA® (nilotinib) Medication Guide.

What does drug intolerance mean?
In rare cases, certain side effects may make it difficult for patients to stay on their Ph+ CML medication. Patients who can no longer stay on treatment because of side effects are said to have drug intolerance.

- Some side effects can go away with time, be managed with help from your doctor, or can be tolerated
- Some side effects may be damaging to your health or may be so bothersome they keep you from taking your treatment as prescribed
- It’s very important that you talk to your doctor or nurse about any side effects you may be experiencing while taking TASIGNA. Do not change your dose of TASIGNA or stop taking it without talking to your doctor first.

Please 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® (nilotinib). For more information, ask your doctor or pharmacist.

In basketball, I relied on the skyhook. In treating my Ph+ CML, I rely on TASIGNA.

– KAREEM ABDUL-JABBAR
NBA ALL-TIME LEADING SCORER

Kareem Abdul-Jabbar is an actual Ph+ CML patient taking TASIGNA and was previously treated with imatinib. He is compensated by Novartis.
How to take TASIGNA

TASIGNA® (nilotinib) comes in 150-mg or 200-mg capsules. Your doctor will prescribe the dosage that’s appropriate for you.

- Don’t eat two hours before and one hour after your dose.
- Make sure to swallow the pills whole, followed by a full glass of water.
- Wait approximately 12 hours between doses.
- The usual dose is to take 2 capsules in the morning and 2 capsules in the evening on an empty stomach. Be sure to follow your doctor’s instructions.

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**How to take TASIGNA (Continued)**

Avoid grapefruit, grapefruit juice, and any supplement containing grapefruit extract while taking TASIGNA® (nilotinib). Food and grapefruit products increase the amount of TASIGNA in your body.

Avoid taking other medicines or other supplements with TASIGNA.

If you miss a dose, take your next dose as scheduled. Do not take a double dose to make up for a missed dose.

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

Talk to your doctor or pharmacist about all other medication(s) you may be taking, including prescription medicines, over-the-counter medicines, vitamins, and herbal supplements, since they may affect how TASIGNA works and increase your chance of serious and life-threatening side effects.

**Important Safety Information**

TASIGNA may cause serious side effects, including:

- **Liver damage:** Symptoms include yellow skin and eyes
- **Pancreas inflammation (pancreatitis):** Symptoms include sudden stomach area pain with nausea and vomiting
- **Bleeding in the brain:** Symptoms include sudden headache, changes in your eyesight, not being aware of what is going on around you and becoming unconscious

Please see Important Safety Information including **Boxed WARNING** on pages 44-47. Please [click here](#) for full Prescribing Information, and the TASIGNA® (nilotinib) Medication Guide.
What to expect with treatment

Throughout your treatment with TASIGNA® (nilotinib), your doctor will likely prescribe regular tests. This may include hematologic, cytogenetic, or molecular tests. The results of these tests will let you and your doctor know if you’re reaching your treatment milestones when you should be. It’s important to know that everyone will reach treatment milestones at his or her own pace.

According to national guidelines, an appropriate response at three months is partial cytogenetic response (PCyR).

Tools to help stay on track with treatment

These tools were created to help you determine when to take TASIGNA® (nilotinib), and remember upcoming appointments and refills:

Important Safety Information

TASIGNA may cause serious side effects, including:

- Tumor Lysis Syndrome (TLS): TLS is caused by a fast breakdown of cancer cells. TLS can cause you to have:
  - Kidney failure and the need for dialysis treatment
  - An abnormal heart beat
  - Your doctor may do blood tests to check you for TLS.
  - Please see Important Safety Information including Boxed WARNING on pages 44-47. Please click here for full Prescribing Information, and the TASIGNA® (nilotinib) Medication Guide.

Track your results with TASIGNA

Use the Tracking Journal included in this kit to start tracking your test results to see that you’re reaching your treatment milestones. Be sure to also jot down any notes or questions you may have for your doctor. Discussing your results with your doctor will help you stay engaged with your treatment, and help you understand if changes to your treatment plan are needed.

The Dosing Wheel

You’ll find your portable dosing wheel in this kit. Use the wheel to help determine your AM and PM dosing times. Once you set your AM time, the wheel will display your PM time. The wheel also shows you when to stop and start eating.

My TASIGNA calendar tool

Personalize your AM and PM TASIGNA dosing schedule and set up reminders for upcoming doctor appointments, lab visits, and even your next refill.

Learn more about the My TASIGNA program on page 39, and at www.My-TASIGNA.com
My TASIGNA

You may find that you would like additional information and support when taking TASIGNA® (nilotinib) and living with Ph+ CML. My TASIGNA is a support program that can help you navigate your treatment journey—whether you’re new to TASIGNA, or have been on treatment for some time.

When you sign up for My TASIGNA, you’ll get:

- Educational resources to help you better understand Ph+ CML and TASIGNA
- Help in understanding testing and treatment milestones related to your condition
- Financial assistance information
- E-mails with tips and support for managing Ph+ CML
- 24/7 access to your account using your computer, tablet or smartphone

Get ongoing information and support. Sign up now by visiting www.My-TASIGNA.com.
Save on your TASIGNA prescription

Monthly co-pay assistance with the Universal Co-Pay Card.*
Patients may be eligible for immediate co-pay savings on their next prescription. Commercially insured patients may pay no more than $10 per month. Annual maximum of $15,000 paid by Novartis per calendar year.

To find out if you are eligible, and to obtain your co-pay card, please call 1-877-677-7756 or visit www.copy.novartisoncology.com.

For additional financial assistance information, visit www.us.TASIGNA.com.

*Limitations Apply. See Program Terms and Conditions. The co-pay offer is not valid under Medicare, Medicaid or any other federal or state program. Novartis reserves the right to rescind, revise, or amend the programs without notice.

www.TASIGNA.com

Visit www.TASIGNA.com for even more ways to get information about TASIGNA and Ph+ CML. Find helpful information and resources to help you on your treatment journey.

TASIGNA Facebook community

Check out the TASIGNA Facebook page to:
• Get the latest news and information about TASIGNA and CML
• Interact with others like you

Patient Assistance Now Oncology

Novartis Oncology is committed to helping patients living with cancer receive the medicine they need. Patient Assistance Now Oncology (PANO) offers quick and easy access to information about our wide range of resources. You can get information about our PANO support program in two ways:
• Call 1-800-282-7630 to speak to one of our knowledgeable staff dedicated to making access to our programs as simple and convenient as possible.
• Visit our website at: www.OncologyAccessNow.com

Start saving on TASIGNA. Visit www.us.TASIGNA.com today.
Other resources

These organizations may be able to provide additional information, connections, and support.

American Cancer Society
www.cancer.org
800-ACS-2345 (800-227-2345)

CancerCare
www.cancercare.org
800-813-HOPE (800-813-4673)

Leukemia & Lymphoma Society
www.lls.org
800-955-4572

National Cancer Institute (NCI)
www.cancer.gov

NCI’s Cancer Information Service
www.cancer.gov/aboutnci/cis
800-4-CANCER (800-422-6237)

National Patient Advocate Foundation
www.npaf.org
202-347-8009

The organizations and websites listed under additional resources 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.

Meet Virginia, Robert and Russ: real TASIGNA patients living with Ph+ CML

The Ph+ CML Story Series is a documentary series, shot by award-winning filmmakers. It follows the everyday lives of three different patients at different stages in their treatment journeys. Watch the videos at www.My-TASIGNA.com to learn how they’re managing the various aspects of the condition, from treatment and testing to working and relationships.
TASIGNA® (nilotinib) Indications

TASIGNA is a prescription medicine used to treat adults who have:
• Newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase. The effectiveness of TASIGNA in these patients is based on a study that measured two types of response to treatment (cytogenetic and molecular).
• Ph+ CML in chronic phase and accelerated phase who are no longer benefiting from, or did not tolerate, other treatment including GLEEVEC® (imatinib mesylate). The effectiveness of TASIGNA in these patients is based on a study that measured two types of response to treatment (hematologic and cytogenetic).

IMPORTANT SAFETY INFORMATION ABOUT TASIGNA® (nilotinib) Capsules

What is the most important information to know about prescription TASIGNA?

TASIGNA can cause QT prolongation, a possible life-threatening heart problem. QT 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 QT prolongation.

• Your doctor should check your heart with a test called an electrocardiogram (ECG):
  o Before starting TASIGNA
  o 7 days after starting TASIGNA
  o With any dose changes
  o Regularly during TASIGNA treatment

• 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 chance for serious and life-threatening side effects. Do not take any other medicines 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 chance 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.
**IMPORTANT SAFETY INFORMATION**

**Before taking TASIGNA® (nilotinib), tell your doctor about all of your medical conditions, including if you:**
- Have a heart disorder or are taking medication for the heart
- 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 an irregular heartbeat
- Have QT prolongation or a family history of it
- Have liver problems
- Have had a pancreas disorder known as pancreatitis
- Know that you suffer from low blood levels of electrolytes, such as potassium or magnesium
- Have had a surgical procedure involving the removal of the entire stomach (total gastrectomy)
- Are lactose-intolerant
- Most patients who have mild or moderate lactose intolerance can take TASIGNA®

**TASIGNA may cause serious side effects, including:**
- **Low blood counts:** Low blood counts are common with TASIGNA. Your doctor will check your blood counts regularly during treatment with TASIGNA. Symptoms of low blood counts include:
  - Unexplained bleeding or bruising
  - Blood in urine or stool
  - Unexplained weakness
- **QT prolongation:** Call your doctor right away if you feel lightheaded, faint or have an irregular heartbeat while taking TASIGNA. These can be symptoms of QT prolongation, a possible life-threatening heart problem
- **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
  - Your leg feels numb
  - Problems with decreased blood flow to your legs
- **Liver damage:** Some patients who have had liver damage due to a viral infection that attacks the liver (hepatitis) have had liver problems with TASIGNA. These include:
  - Unexplained weight gain
  - Rapid weight gain, and swelling of the skin or other parts of the body
  - Night sweats
  - Fever
  - Runny or stuffy nose, sneezing, sore throat
  - Muscle and joint pain
  - Constipation
  - Cough
- **Lung cancer (peripheral T-cell lymphoma):** Some patients with this type of cancer have had serious lung problems with TASIGNA. These include:
  - Trouble breathing
  - Chest pain or discomfort
  - Numbness or weakness
  - Problems walking or speaking
  - Leg pain
  - Changes in your eyesight, not being aware of what is going on around you and becoming unconscious

**Common side effects**

Most patients experience side effects at some time. Some common side effects that may experience include:
- **Low blood count**
  - Night sweats
  - Rash
  - Headache
  - Itching
  - Vomiting
  - Diarhea
  - Fever
  - Night sweats
  - Unexplained weakness
- **Fluid Retention:** Call your doctor right away if you have any of the following symptoms:
  - Fluid retention. Symptoms of fluid retention include shortness of breath, rapid weight gain, and swelling

**Tumor Lysis Syndrome (TLS):** TLS is caused by a fast breakdown of cancer cells. TLS can cause you to have:
- Kidney failure and the need for dialysis treatment
- An abnormal heart beat

Your doctor may do blood tests to check you for TLS. Blood testing tells your doctor about signs and symptoms of bleeding.

**Fluct Retention:** Your body may hold too much fluid (fluid retention). Symptoms of fluid retention include shortness of breath, rapid weight gain, and swelling

**Common side effects**

Most patients experience side effects at some time. Some common side effects that may experience include:
- **Low blood count**
- **Rash**
- **Headache**
- **Itching**
- **Vomiting**
- **Diarrhea**
- **Fever**
- **Night sweats**

Tell your doctor if you have any side effect that bothers you or does not go away. These are not all 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.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Take TASIGNA exactly as your doctor tells you to take it. Do not change your dose or stop taking TASIGNA unless your doctor tells you to. TASIGNA is a long-term treatment

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

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:
- An antacid that contains such as calcium carbonate, cimetidine, ranitidine, and simethicone to reduce the amount of acid in the stomach: Take these medicines about 10 hours before or after you take TASIGNA
- An antacid that contains aluminum hydroxide, magnesium hydroxide, or magnesium trisilicate 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 visit www.TASIGNA.com for full Prescribing Information including the Board WARNING, and the TASIGNA® (nilotinib) Medication Guide.**
To learn more about Ph+ CML and TASIGNA® (nilotinib), visit www.TASIGNA.com