Patient portrayal

Patient portrayal

YOUR BLOOD DEMANDS TO BE HEARD.

A guide to speaking up about Ph+ CML in chronic phase as you start TASIGNA

Your blood can't speak for itself. That's why you have to be its voice.

Whether you've been recently diagnosed with Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase (Ph+ CML-CP) or your doctor has decided it's time for you to switch to TASIGNA® (nilotinib) capsules from another medication, the information in this guide can help you have your say when it comes to talking about the disease and the clinical results of TASIGNA. To learn more, visit **www.tasigna.com.**

Approved Uses

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

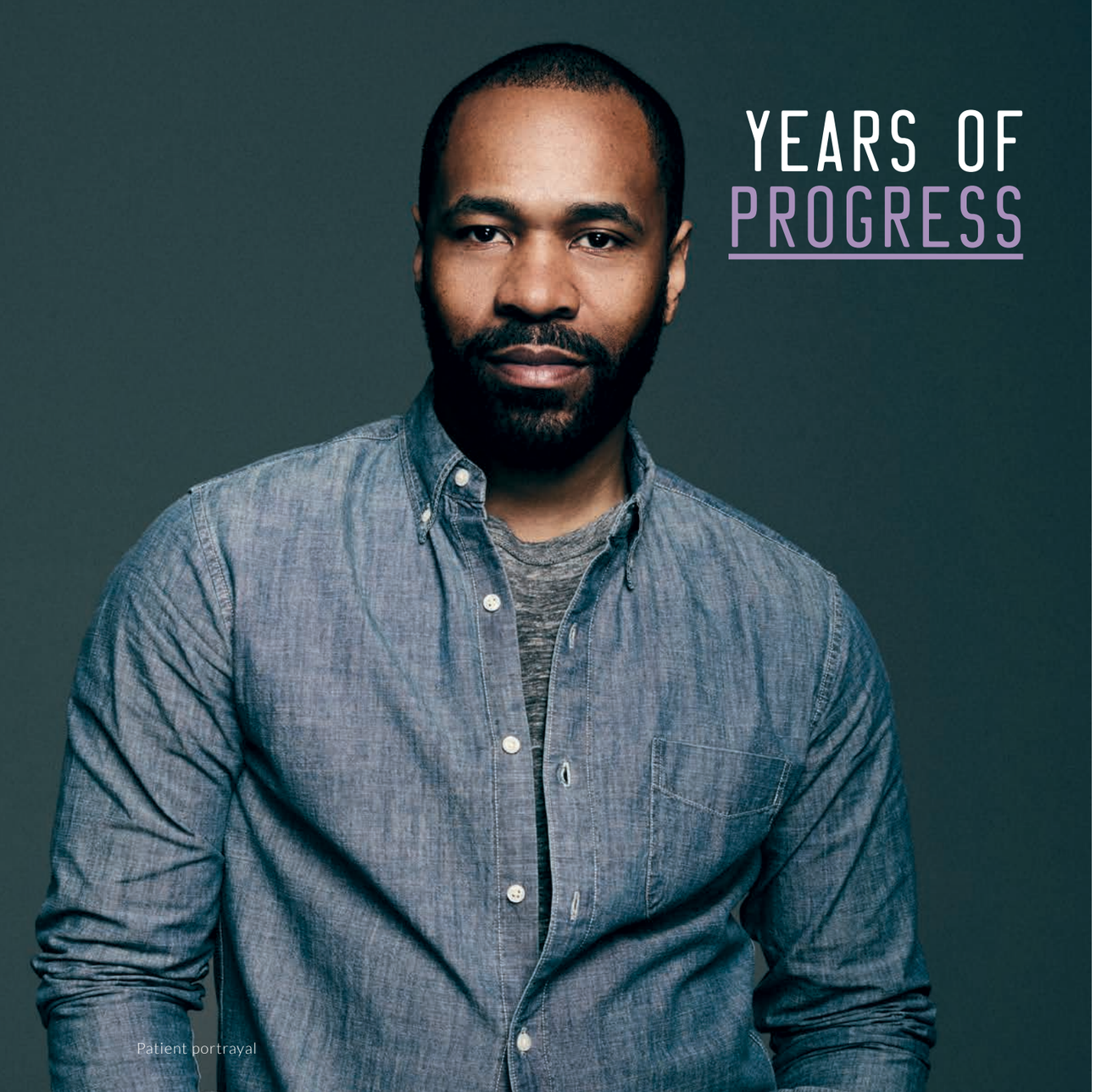
- Adults with newly diagnosed Philadelphia chromosome–positive (Ph+) chronic myeloid leukemia (CML) in chronic phase
- Adults with Ph+ CML in chronic phase and accelerated phase who no longer benefit from, or did not tolerate, other treatment, including GLEEVEC® (imatinib)

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

Please see Important Safety Information about TASIGNA® (nilotinib) capsules, including Boxed WARNING, throughout this brochure and Summary of Important Information on pages 22–29.

Tasigna (nilotinib) 150mg, 200mg capsules



Patient portrayal

IN TREATING Ph+ CML IN CHRONIC PHASE.

Since 2001, a class of prescription medications called tyrosine kinase inhibitors (TKIs) has helped transform Ph+ CML from a type of leukemia that was life-threatening into a manageable disease that more people are living with.

All this progress has led some people to talk about Ph+ CML as a "good cancer." But in reality, there's no such thing. That's why it's important to make sure your blood is getting the treatment—and the attention—it deserves.

That's where TASIGNA® (nilotinib) capsules come in. TASIGNA has been proven effective for more than 10 years in treating Ph+ CML in chronic phase among two key groups:

- People who were newly diagnosed
- People who switched to TASIGNA from another medication due to side effects or because they were no longer responding to their prior treatment

There's a lot to learn about Ph+ CML. This guide is a good place to start. To help you speak the language of Ph+ CML, see the glossary on page 34.

If you have any questions, be sure to speak with your doctor. You can also visit **www.tasigna.com** to learn more.

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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THE BASICS:

PHILADELPHIA CHROMOSOME-POSITIVE CHRONIC MYELOID LEUKEMIA.

Ph+ CML seems to come out of nowhere. After a routine blood test, your doctor tells you that your white blood cell count is sky high. Next thing you know, you're hearing the word "leukemia."

Your diagnosis comes as a shock. It also comes with a lot of terms that are likely to be unfamiliar to you. Some of the basics of Ph+ CML are outlined in the following pages.

THE FACTS ABOUT Ph+ CML.

What is chronic myeloid leukemia (CML)?

CML is considered chronic because the disease progresses slowly. The term ***myeloid*** has to do with, or is related to, bone marrow—a sponge-like tissue found in the center of most bones.

Here are some facts about CML you may want to know:

What you should know about Ph+ CML

More than 95% of people with CML have what is called the "Philadelphia chromosome." These patients have Ph+ CML, which stands for Philadelphia chromosome–positive chronic myeloid leukemia.

Many people diagnosed with Ph+ CML early on do not have any obvious signs or symptoms.

What causes Ph+ CML?

You're not born with Ph+ CML. It's also not handed down from one generation to the next. So what causes it?

Ph+ CML has to do with a change in chromosomes in your body. As your cells wear out, they make copies of themselves. Each cell copies everything inside it, including its chromosomes. The cell then splits in 2—creating 2 identical cells.

Although it's not known why, sometimes a mistake happens when the cell is copying itself. For example:

- A piece of 1 chromosome in a cell may break off and attach to another chromosome
- Or pieces from 2 different chromosomes may swap places. In Ph+ CML, pieces from chromosomes 9 and 22 (in humans, each cell has 23 chromosome pairs) trade places. This creates a new abnormal chromosome 22—called the Philadelphia chromosome

Either of these instances can create an abnormal gene called *BCR-ABL1*. This produces an abnormal protein—also called BCR-ABL.

What happens in Ph+ CML?

Think of the BCR-ABL protein like a light switch:

- The BCR-ABL protein "turns on" the bone marrow
- The bone marrow starts making too many immature white blood cells
- These immature white blood cells grow abnormally. Your doctor may call them *leukemic cells*

Here's what happens inside your body when you have Ph+ CML:

- The leukemic cells start to grow and divide
- They build up in the bone marrow, move into the bloodstream, and travel throughout the body
- Over time, excess leukemic cells crowd out healthy red blood cells and platelets
- This can cause problems such as anemia, bruising easily, bleeding that takes longer to stop, and a greater chance of infections

The phases of Ph+ CML

There are 3 phases of Ph+ CML, which are based on the percentage of immature white blood cells, specifically called "blast cells," in the bone marrow compared to other blood cells.

- **Chronic phase:** Less than 10% of blood cells in the bone marrow are leukemic cells*
- **Accelerated phase:** 10–19% of blood cells in the bone marrow are leukemic cells*
- **Blast phase:** 20% or more of blood cells in the bone marrow are leukemic cells*

Most adults are diagnosed in chronic phase, which is the first phase of Ph+ CML. Importantly, most people in this phase respond to treatment. Left untreated, Ph+ CML in chronic phase will progress to the accelerated phase. That's why it's important to start treatment sooner rather than later.

Speaking the language of Ph+ CML

You'll find a glossary of terms in the back of this guide. Of course, if you have any questions, be sure to speak with your doctor.

*Based on World Health Organization criteria.

TREATMENT MILESTONES.

The milestones timeline shows an ideal response to treatment, which your doctor may discuss with you. The illustrations are designed to help you picture how your blood counts may come down over time with treatment. The dots represent the number of *BCR-ABL1* cells in the body.

Keep in mind, not every patient will reach these treatment milestones or reach them at the same time.

At diagnosis: Baseline

- Initial tests likely show a high level of blood cells with the abnormal gene *BCR-ABL1*
- Your doctor will use this number as a baseline—or starting point. Baseline is considered *BCR-ABL1* 100%. This means that **100 out of 100 cells have the *BCR-ABL1* gene**

At 3 months and 6 months on treatment

- Your doctor may see if you have an early molecular response
- This means the amount of *BCR-ABL1* is less than or equal to (≤) 10% of all the cells in your blood compared to baseline. In this case, **10 out of every 100 cells have the *BCR-ABL1* gene**

At 12 months and after 15 months on treatment

- Your doctor may see if you've had a complete cytogenetic response (CCyR)
- This means the amount of *BCR-ABL1* is ≤1% of all the cells in your blood. In other words, **1 out of every 100 cells has the *BCR-ABL1* gene compared to baseline**

At 18 months on treatment

- Your doctor may see if you have achieved a major molecular response (MMR)
- With MMR, the amount of *BCR-ABL1* in the blood is ≤0.1%. **This means that 1 out of every 1000 cells has the *BCR-ABL1* gene**

Patient portrayal

STARTING YOUR FIRST TREATMENT FOR Ph+ CML.

You've been recently diagnosed with Ph+ CML. Now what? It's important to start on the medication your doctor has prescribed.

The following section provides an overview of treatment goals and information about clinical studies conducted on TASIGNA® (nilotinib) capsules.

Tasigna® (nilotinib) 150mg, 200mg capsules


Patient portrayal

YOUR BLOOD DEMANDS RESULTS.

If you've been prescribed TASIGNA as your first medication for Ph+ CML in chronic phase, here are results you may want to know

TASIGNA® (nilotinib) capsules has been proven effective in treating Ph+ CML-CP for more than 10 years. Now that your doctor has prescribed TASIGNA as your first treatment for Ph+ CML-CP, here's some information that you may find helpful.

Achieving a response

Every patient is unique and your doctor will need to discuss the treatment goals that are within your reach. Some common goals include:

- Getting your blood cell counts back within normal ranges
- Reducing the number of leukemic cells in your body
- Reducing the amount of the BCR-ABL protein to a level that is undetectable

Your doctor may talk about achieving what's called a "molecular response." This means the number of cells in your body with the *BCR-ABL1* gene is going down. The lower the number, the better.

In clinical trials, TASIGNA was shown to be an effective treatment for Ph+ CML-CP based on the following responses to the medication:

- An early response to treatment at 3 months
- A major molecular response (MMR) at 1 year
- A sustained molecular response by 5 years

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
- **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

Please see Important Safety Information about TASIGNA® (nilotinib) capsules, including Boxed WARNING, throughout this brochure and Summary of Important Information on pages 22–29.

Tasigna® (nilotinib) 150mg, 200mg capsules

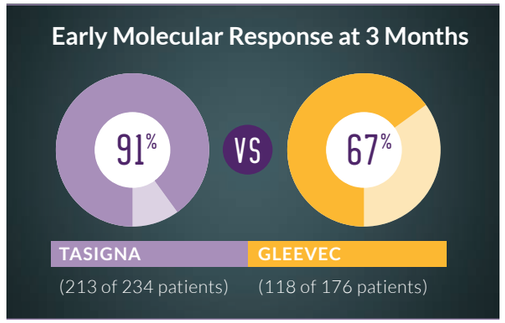
CLINICAL RESULTS AMONG THOSE NEWLY DIAGNOSED.

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.

Early response to TASIGNA

Early response means that at 3 months your *BCR-ABL1* levels are lower than when you started treatment.

In a clinical study, 9 out of 10 adults (213 of 234 patients) on TASIGNA achieved an early molecular response (*BCR-ABL1* ≤10%) at 3 months. This means that 10 out of every 100 cells have the *BCR-ABL1* gene.

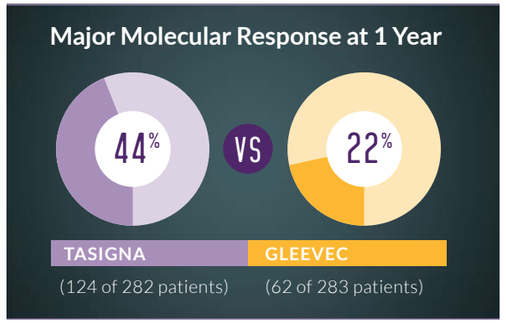


Early response is a milestone, which more patients reached with TASIGNA than with GLEEVEC® (imatinib mesylate). In addition, patients who achieved a molecular response at 3 months (*BCR-ABL1* ≤10%) were more likely to achieve a major molecular response (MMR) at 1 year (*BCR-ABL1* ≤0.1%).

Twice as many achieved MMR with TASIGNA at 1 year

MMR means that the amount of *BCR-ABL1* in your bone marrow is 1000-fold lower than your baseline, when you started treatment. This is a good sign when you have Ph+ CML-CP.

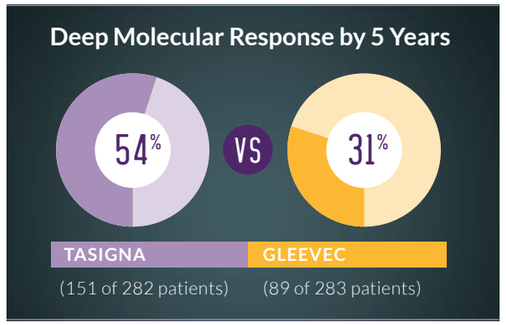
In a clinical trial, twice as many adults who took TASIGNA achieved MMR (*BCR-ABL1* ≤0.1%) 1 year into the clinical trial than patients who took GLEEVEC. With MMR, *BCR-ABL1* is ≤0.1%. This means that 1 out of every 1000 cells has the *BCR-ABL1* gene.



Sustained response to TASIGNA by 5 years

A clinical study showed that more than half of those on TASIGNA (151 of 282 patients, or 54%) achieved a deep molecular response (DMR) by 5 years.

Your doctor may refer to this as MR4.5 (*BCR-ABL1* ≤0.0032%). This means that 1 out of every 32,000 cells has the *BCR-ABL1* gene.



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

- **Liver Problems:** TASIGNA can increase your risk of liver problems. People who have had liver problems in the past may be at risk for getting liver problems with TASIGNA. Call your doctor, or get medical help right away if you develop any symptoms of liver problems including stomach area (abdominal) pain, yellow skin/eyes, and dark-colored urine
- **Tumor Lysis Syndrome (TLS):** TLS is caused by a fast breakdown of cancer cells. Your doctor may do blood tests to check you for TLS. TLS can cause you to have kidney failure (with the need for dialysis treatment) and/or an abnormal heartbeat
- **Bleeding Problems:** Serious bleeding problems and death have happened during treatment with TASIGNA. Call your doctor right away if you develop signs and symptoms of bleeding such as uncontrolled bleeding, changes in eyesight, unconsciousness, sudden headache, or sudden confusion about your surroundings
- **Total Gastrectomy:** Tell your doctor if you have had a surgical procedure involving the removal of the entire stomach (total gastrectomy). Your doctor may need to change your dose

Please see Important Safety Information about TASIGNA® (nilotinib) capsules, including Boxed WARNING, throughout this brochure and Summary of Important Information on pages 22–29.

Tasigna® (nilotinib) 150mg, 200mg capsules

Patient portrayal

MAKING THE SWITCH FROM YOUR PRIOR MEDICATION.

There are a number of reasons why, together with your doctor, you are switching from your prior medication to TASIGNA® (nilotinib) capsules for Ph+ CML. On the following pages, you'll learn why now is the time to move on to your next treatment option.

Tasigna® (nilotinib) 150mg, 200mg capsules


Patient portrayal

SWITCHING TO TASIGNA.

If you're switching to TASIGNA from another medication that wasn't working for you, it can help to understand why

TASIGNA® (nilotinib) capsules is a prescription medicine used to treat adults with Ph+ CML in chronic phase or accelerated phase who no longer benefit from, or did not tolerate, other treatment, including GLEEVEC® (imatinib).

Why the switch?

You and your doctor may have discussed any of the following reasons as to why it is time to switch from your prior treatment for Ph+ CML:

- **Lack of response:** Your body is no longer responding to treatment with the prior medication
- **Drug resistance:** Over time, your body has lost its response to the prior medication. Your doctor may have referred to this as drug resistance
- **Side effects:** You are experiencing side effects, such as diarrhea, nausea, vomiting, and severe muscle cramps
- **Drug intolerance:** Your side effects are so bothersome that they may keep you from taking the prior medication. Once your doctor determines that your body can no longer tolerate the side effects of the prior medication, it is time to try another treatment option

Why TASIGNA?

In a clinical trial, TASIGNA was shown to be effective among patients who had taken GLEEVEC® (imatinib mesylate) first and then switched to TASIGNA.

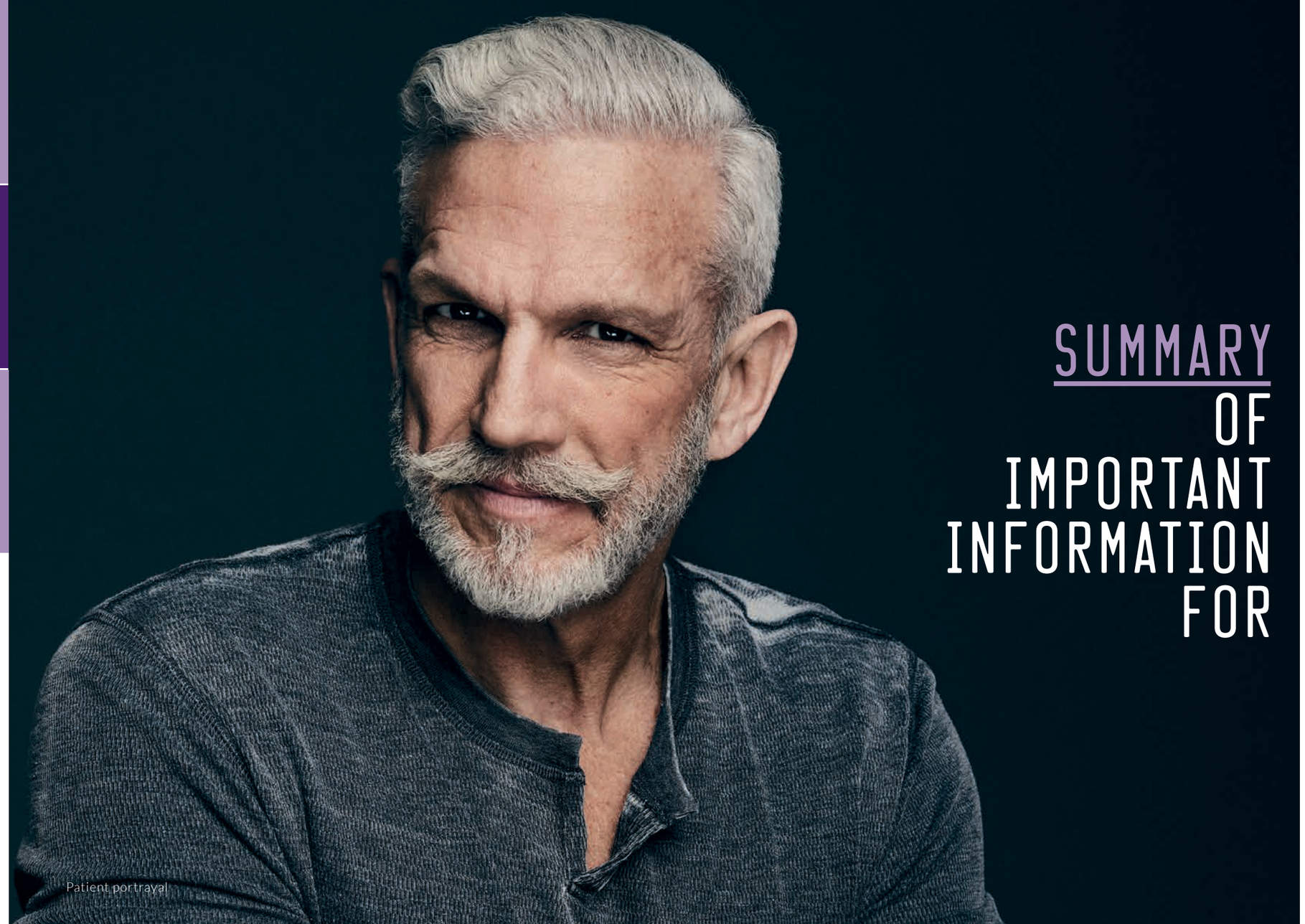
At the time of the study in the mid-2000s, major cytogenetic response (MCyR) was the measured response. Fifty-one percent of Ph+ CML patients (164 of 321 patients) in chronic phase achieved MCyR with TASIGNA. Later studies measured response using major molecular response (MMR) and MR4.5.

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

- **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

Please see Important Safety Information about TASIGNA® (nilotinib) capsules, including Boxed WARNING, throughout this brochure and Summary of Important Information on pages 22–29.

Tasigna® (nilotinib) 150mg, 200mg capsules



Patient portrayal

SUMMARY OF IMPORTANT INFORMATION FOR

Tasigna®
(nilotinib) 150mg, 200mg capsules

In this section, you'll learn the most important information you should know about TASIGNA® (nilotinib) capsules, including possible side effects.

SUMMARY OF IMPORTANT INFORMATION FOR TASIGNA® (NILOTINIB) 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.

<u>In females who are able to become pregnant:</u>

- 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 22–29.

Tasigna® (nilotinib) 150mg, 200mg capsules

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.

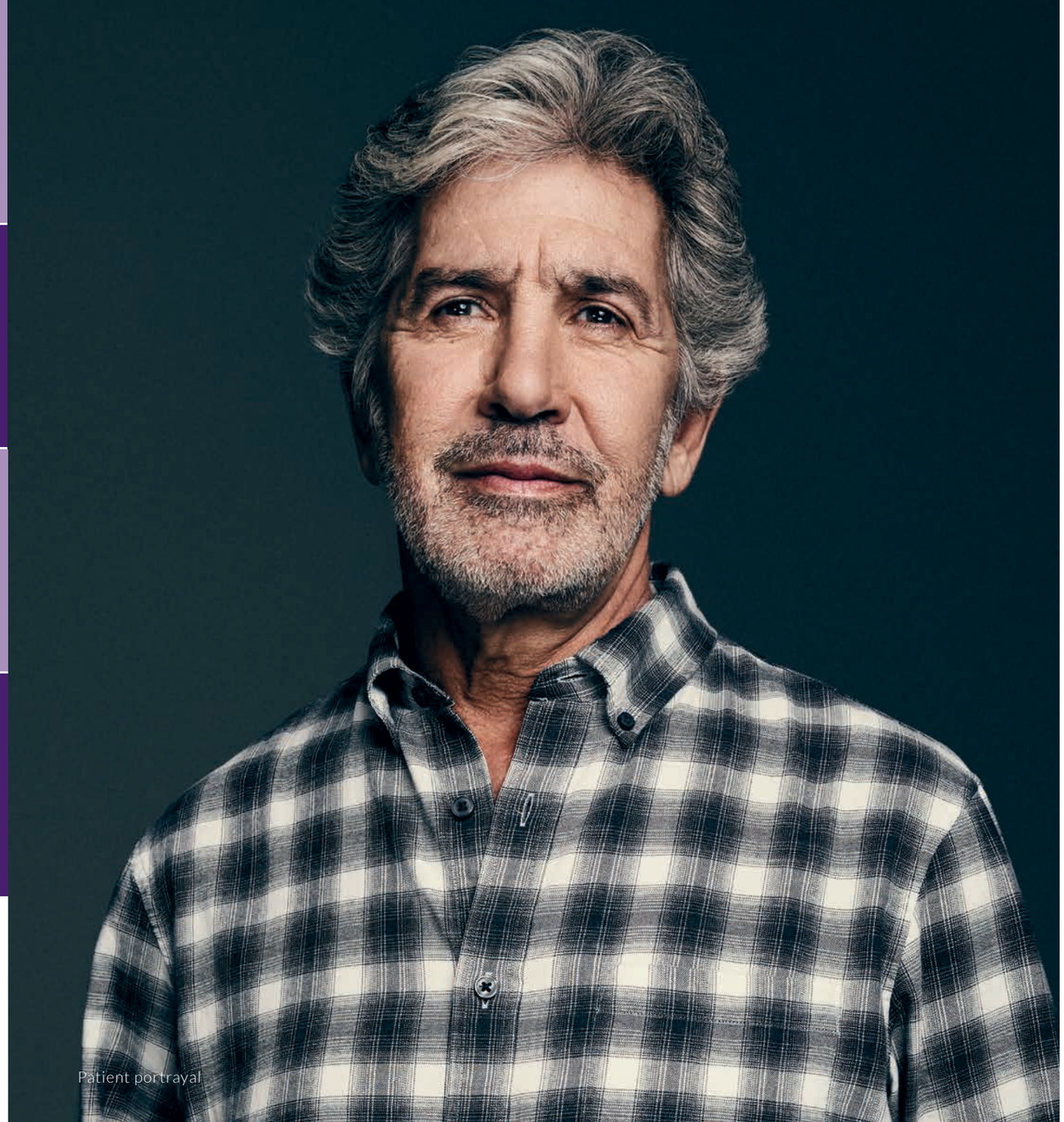
- Your healthcare provider will monitor your CML during treatment with TASIGNA to see if you are in a remission. After at least 3 years of treatment with TASIGNA, your healthcare provider may do certain tests to determine if you continue to be in remission. Based on your test results, your healthcare 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**



Patient portrayal

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

- **Bleeding problems.** Serious bleeding problems and death have happened during treatment with TASIGNA. Tell your healthcare provider right away if you develop any signs and symptoms of bleeding during treatment with 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 may have slower than normal growth during treatment with TASIGNA.
- **The most common side effects of TASIGNA in adults and children include:**
  - nausea
  - rash
  - headache
  - tiredness
  - itching
  - vomiting
  - diarrhea
  - cough
  - constipation
  - muscle and joint pain
  - Runny or stuffy nose, sneezing, sore throat
  - fever
  - night sweats

Side effects in adult patients attempting treatment free remission:

If you and your healthcare provider decide that you can stop taking TASIGNA and try treatment free remission (TFR), you may have more muscle and bone (musculoskeletal) symptoms than before you stopped treatment. Symptoms may include:

- muscle pain
- arm and leg pain
- joint pain
- bone pain
- spine pain

Tell your healthcare provider if you or your child have any side effect that bothers you or does not go away.

These are not all the possible side effects of TASIGNA.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store TASIGNA?

- Store TASIGNA at room temperature between 68°F to 77°F (20°C to 25°C).
- Safely throw away medicine that is out of date or no longer needed.

Keep TASIGNA and all medicines out of the reach of children.

The risk information provided here is not comprehensive. To learn more, talk about TASIGNA with your healthcare provider or pharmacist. The FDA-approved product labeling can be found at www.tasigna.com or call 1-866-411-8274.

Please see Important Safety Information about TASIGNA® (nilotinib) capsules, including Boxed WARNING, throughout this brochure and Summary of Important Information on pages 22–29.

Tasigna® (nilotinib) 150mg, 200mg capsules

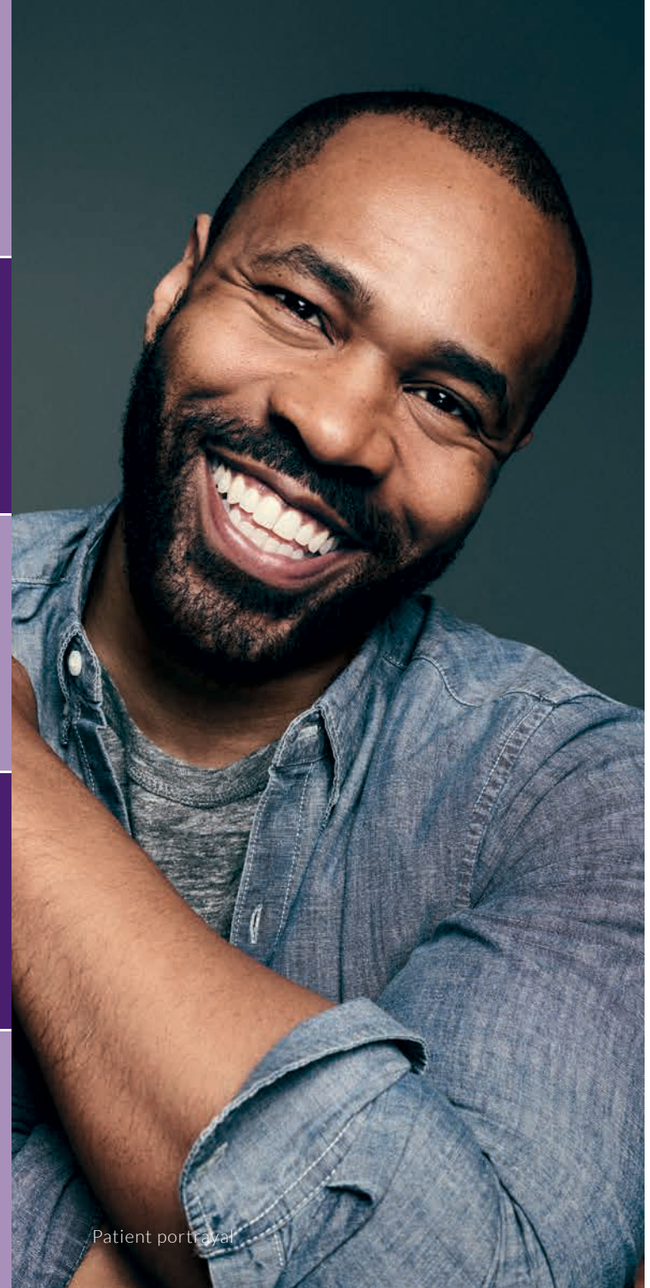
Patient portrayal

SAVINGS THAT SPEAK FOR THEMSELVES.

GETTING YOUR MEDICATION FOR LESS.

Saving on your medication makes for a good starting point. Review the following pages to see how you may be able to save on TASIGNA® (nilotinib) capsules for Ph+ CML from the beginning—and every month after that.

Tasigna® (nilotinib) 150mg, 200mg capsules


Patient portrayal

SAVE FROM THE START.

Get your first month of TASIGNA free
If you are just starting on TASIGNA® (nilotinib) capsules, you can receive your first month free. For your 1 month free trial voucher, visit **www.tasigna.com.** Limitations apply.*

Save on TASIGNA, month after month
If you have private insurance, you could save on TASIGNA every month with our Universal Co-Pay Card.†

- If you're eligible, you may pay as little as $0 per prescription
- Novartis will pay the remaining co-pay, up to $15,000 per calendar year†

To find out if you are eligible to save on TASIGNA—month after month—call **1-877-577-7756** or visit **www.Copay.NovartisOncology.com.**

*1 Month FREE Trial Voucher Terms & Conditions

No purchase required. This free trial is not health insurance. Void where prohibited by law. Product dispensed pursuant to terms and conditions of the voucher. Claim shall not be submitted to any public or private third-party payer of any federal or state healthcare program for reimbursement. Valid only in the US and Puerto Rico. Offer not valid if reproduced or submitted to any other payer. Prescriber ID# required on prescription. It is illegal for any person to sell, purchase or trade, or offer to sell, purchase or trade, or to counterfeit this voucher. **Pharmacist Instructions:** This voucher must accompany a valid prescription. No substitutions permitted. Please dispense at no cost to the patient. For reimbursement, please submit this offer as a primary claim to OPUS Health using BIN# 601341. Do not submit to any other payer, public or private. The information printed above should be used when submitting for reimbursement. For questions, please call the Help Desk at 1-800-364-4767. This voucher is the property of Novartis and IQVIA and must be returned upon request. Both parties reserve the right to rescind, revoke, or amend this program without notice.

Universal Co-pay Card Program Terms & Conditions

Terms and Conditions: The Novartis Oncology Universal Co-pay Program includes the co-pay card, payment card, or rebate with a combined annual limit of $15,000. Patient is responsible for any costs once the limit is reached in a calendar year. This offer is only available to patients with private insurance. The program is not available for patients who: (i) are enrolled in Medicare, Medicaid, TRICARE, VA, DoD, or any other federal or state health care program; (ii) are not using insurance coverage at all; (iii) are enrolled in an insurance plan that reimburses for the entire cost of the drug; or (iv) where product is not covered by patient's insurance. The value of this program is exclusively for the benefit of enrolled patients and is intended to be credited toward patient out-of-pocket obligations, including applicable copayments, coinsurance, and deductibles. Proof of purchase may be required. Patient may not seek reimbursement for the value received from this program from other parties, including any health insurance program or plan, flexible spending account, or health care savings account. Patient is responsible for complying with any applicable limitations and requirements of his/her health plan related to the use of the program. Program is not valid where prohibited by law. Valid only in the United States and Puerto Rico. Offer is not valid for California or Massachusetts residents for certain medications. This program is not health insurance. This program may not be combined with any third-party rebate, coupon, or offer. Novartis reserves the right to rescind, revoke, or amend the program and discontinue support at any time without notice.

Patient Instructions: After enrollment in the program, present this card and your insurance card along with a valid prescription at any participating pharmacy or through mail order. Patients are responsible for up to the first $25 (specific offer varies by brand) and Novartis pays up to $15,000 per calendar year. If patient reaches the maximum annual cap per calendar year of $15,000, patient will be responsible for the difference.

When you use this card, you are certifying that you understand and agree to comply with the program Terms and Conditions above.

Direct patient questions to **1-877-577-7756**.

† Limitations apply. This offer is only available to patients with private insurance. The program is not available for patients who are enrolled in Medicare, Medicaid, or any other federal or state health care program. Novartis reserves the right to rescind, revoke, or amend this program without notice. For full Terms and Conditions, visit www.Copay.NovartisOncology.com or call 1-877-577-7756.

Please see Important Safety Information about TASIGNA® (nilotinib) capsules, including Boxed WARNING, throughout this brochure and Summary of Important Information on pages 22–29.

Tasigna® (nilotinib) 150mg, 200mg capsules

Patient portrayal

SPEAKING THE LANGUAGE OF Ph+ CML.

Here are definitions of some of the terms in this guide. You may find it helpful to get familiar with these words, as your doctor may use them in your conversations. The glossary may also be helpful in explaining Ph+ CML to your family and friends.

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.

Chromosome: The DNA found in a cell. Human cells normally have 23 pairs of chromosomes.

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

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* ≤0.0032%). This means that 1 out of every 32,000 cells has the *BCR-ABL1* gene.

Intolerance: When side effects of a medication become so bothersome, a patient can no longer take the medication.

Leukemic cells: Diseased white blood cells that grow abnormally.

Major cytogenetic response (MCyR): 0% to 35% of the cells in the bone marrow have the Philadelphia chromosome.

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

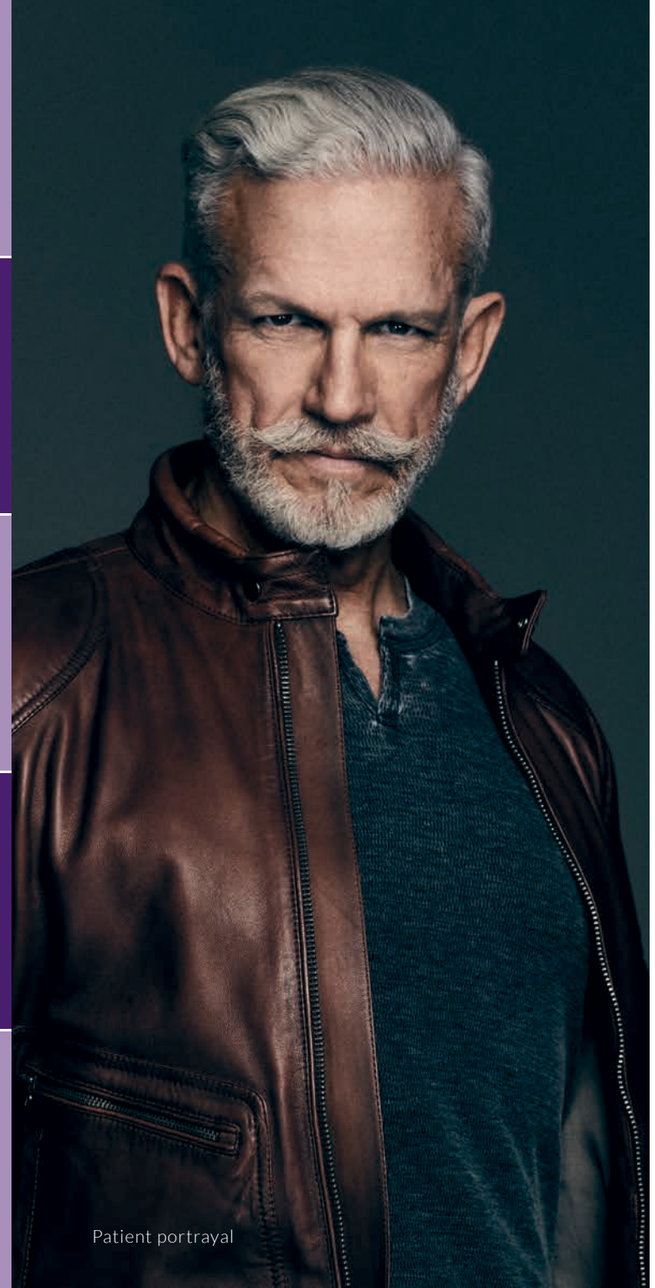
Molecular response: Refers to a decrease in the number of cells in the blood with *BCR-ABL1*.

Platelets: Very small cells in the bone marrow that form blood clots and control bleeding.

Red blood cells: Move oxygen from the lungs to the body.

Resistance: When a medical condition does not respond to treatment or stops responding to treatment.

White blood cells: Help your body fight infection and disease.



Patient portrayal

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

- **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

- **Drug Interactions:** TASIGNA can interact with many medicines and supplements. This may increase your chances for serious and life-threatening side effects. Tell your doctor about all the medicines you take including prescription and over-the-counter medicines, vitamins, and herbal supplements

  If you need to take antacids (medicines to treat heartburn) do not take them at the same time that you take TASIGNA. If you take:
  - A medicine to block the amount of acid produced in the stomach (H2 blocker): Take these medicines about 10 hours before you take TASIGNA or about 2 hours after you take TASIGNA
  - An antacid that contains aluminum hydroxide, magnesium hydroxide, and simethicone to reduce the amount of acid in the stomach: Take these medicines about 2 hours before or about 2 hours after you take TASIGNA

- **Common Side Effects in Adults and Children Include:**
  - Nausea
  - Diarrhea
  - Rash
  - Cough
  - Headache
  - Constipation
  - Tiredness
  - Muscle and joint pain
  - Itching
  - Vomiting
  - Fever
  - Night sweats
  - Runny or stuffy nose, sneezing, sore throat

- **Side Effects in Adults Attempting TFR:** If you and your doctor decide that you can stop taking TASIGNA and try TFR, you may have more muscle and bone (musculoskeletal) symptoms than before you stopped treatment. Symptoms may include muscle pain, bone pain, arm and leg pain, spinal pain, and joint pain

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

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit **www.fda.gov/medwatch**, or call 1-800-FDA-1088.

Please see Important Safety Information about TASIGNA® (nilotinib) capsules, including Boxed WARNING, throughout this brochure and Summary of Important Information on pages 22–29.

Tasigna® (nilotinib) 150mg, 200mg capsules

Patient portrayal

YOUR BLOOD DEMANDS TO BE HEARD.

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To learn more about Ph+ CML and TASIGNA, visit **www.tasigna.com.**

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