

My CML Circle™: A Novartis Co-Pay Assistance Program For Ph+ CML Patients

Paying for your Ph+ CML treatment just got easier—with My CML Circle Co-Pay Assistance Program

- My CML Circle Co-Pay Assistance Program provides support for you throughout your Philadelphia chromosome–positive (Ph+) chronic myeloid leukemia (CML) treatment journey.

My CML Circle Co-Pay Assistance Program offers you:

- A valuable co-pay assistance card designed to help support you throughout your Ph+ CML treatment by simply calling toll-free at **1-877-966-2745**, or by visiting **www.mycmlcircle.com**
- Informative Ph+ CML brochures that cover topics like managing side effects and the best way to communicate with your healthcare provider
- Regular updates about staying on Ph+ CML treatment, healthy living tips, My CML Circle Co-Pay Assistance Program features, plus other useful information
- No proof of income is required to participate in this program

Provides co-pay assistance to participating Ph+ CML patients

- If you are starting on or currently taking GLEEVEC 400 mg daily, you can receive up to \$15 per prescription refill for 12 refills. This is a total savings of up to \$180 of co-pay assistance.
- If you are already taking a higher dose of GLEEVEC or your healthcare provider increases your dose of GLEEVEC, you can receive up to \$25 per prescription refill for 12 refills. This is a total savings of up to \$300 of co-pay assistance.
- If you are currently taking TASIGNA or should your healthcare provider transition you to TASIGNA, you can receive up to \$50 per prescription refill for 12 refills. This is a total savings of up to \$600 of co-pay assistance.
- Please note that you may not receive the maximum co-pay assistance for each prescription. The total value of your co-pay assistance card is determined by your co-pay.

Enroll and participate in My CML Circle Co-Pay Assistance Program by calling toll-free **1-877-966-2745**, or by visiting **www.mycmlcircle.com**, and you will be mailed a co-pay assistance card and welcome materials.

GLEEVEC® (imatinib mesylate) tablets are indicated for the treatment of newly diagnosed adult patients with Philadelphia chromosome–positive chronic myeloid leukemia (Ph+ CML) in the chronic phase (CP). Follow-up is limited to 5 years. GLEEVEC tablets are also indicated for the treatment of patients with Ph+ CML in blast crisis (BC), accelerated phase (AP), or in CP after failure of interferon-alpha therapy.

TASIGNA (nilotinib) 200-mg capsules are indicated for the treatment of chronic phase and accelerated phase Philadelphia chromosome–positive (Ph+) chronic myelogenous leukemia (CML) in adult patients resistant or intolerant to prior therapy that included imatinib. The effectiveness of TASIGNA is based on hematologic and cytogenetic response rates. There are no controlled trials demonstrating a clinical benefit, such as improvement in disease-related symptoms or increased survival.

Please see Important Safety Information for GLEEVEC and TASIGNA inside, including **Boxed WARNING** for TASIGNA, full Prescribing Information enclosed, and the TASIGNA Medication Guide you received with your prescription.

Important Information about TASIGNA

TASIGNA (nilotinib) 200-mg capsules are indicated for the treatment of chronic phase and accelerated phase Philadelphia chromosome–positive (Ph+) chronic myelogenous leukemia (CML) in adult patients resistant or intolerant to prior therapy that included imatinib. The effectiveness of TASIGNA is based on hematologic and cytogenetic response rates. There are no controlled trials demonstrating a clinical benefit, such as improvement in disease-related symptoms or increased survival.

What is the most important information to know about TASIGNA?

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

Your doctor should check your heart with a test called an “ECG”:

- Before taking TASIGNA
- 7 days after starting TASIGNA
- Regularly during treatment
- After any dose changes

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

- **Take TASIGNA on an empty stomach.**

DO NOT TAKE TASIGNA WITH FOOD

Food can affect the levels of TASIGNA in your body, which can lead to serious side effects. Taking TASIGNA on an empty stomach may lower your chances of having a possibly life-threatening heart problem called QT prolongation.

QT prolongation causes an irregular heartbeat, which may lead to sudden death.

Take TASIGNA:

- At least 2 hours after eating any food, and
- After taking TASIGNA, wait at least 1 hour before eating any food
- **Avoid grapefruit, grapefruit juice, and any supplement containing grapefruit extract while taking TASIGNA.** Food and grapefruit products increase blood levels of TASIGNA in your body
- **Avoid taking other medicines, vitamins, or herbal supplements with TASIGNA that can also cause QT prolongation**

TASIGNA is a prescription medication.

TASIGNA comes in 200 mg capsules. Your doctor will prescribe 400 mg of TASIGNA to be taken twice a day for a total daily dose of 800 mg. Each dose should be taken approximately 12 hours apart.

Swallow TASIGNA capsules whole with water.

- Do not open TASIGNA capsules
- Do not drink grapefruit juice, eat grapefruit, or take supplements containing grapefruit extract. It may affect the levels of TASIGNA in the blood
- If you miss a dose, take your next dose as scheduled. Do not take a double dose to make up for a missed dose

Before taking TASIGNA

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.

Tell your doctor if:

- You have a heart disorder or are taking medication for the heart
- You have an irregular heartbeat
- You have QT prolongation or a family history of it
- You know that you suffer from low blood levels of electrolytes, such as potassium, magnesium, or calcium; or you have a liver or pancreas disorder
- Also tell your doctor if you are pregnant, breast feeding, or lactose-intolerant

Call your doctor right away if you faint or have an irregular heartbeat while taking TASIGNA.

These can be symptoms of QT prolongation.

Call your doctor immediately if you experience any of these symptoms.

Serious side effects

TASIGNA is sometimes associated with serious side effects, with symptoms that include:

- Irregularity in heartbeat or fainting
- Unexplained bleeding or bruising
- Blood in urine or stool
- Unexplained weakness
- Yellow skin and eyes
- Shortness of breath
- Swelling of hands, ankles, feet, or face
- Sudden stomach area pain with nausea and vomiting

Common side effects

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

- Low blood count
- Rash
- Nausea
- Headache
- Itching
- Tiredness
- Diarrhea
- Constipation

Be sure to tell your doctor or pharmacist if you have any side effects during treatment with TASIGNA.

Tell your doctor if you are pregnant or planning to become pregnant. TASIGNA can harm a fetus (unborn baby).

- Women who can get pregnant must use effective birth control during treatment with TASIGNA

Tell your doctor if you are breast-feeding.

Women should not breast-feed while taking TASIGNA.

If you take too much TASIGNA, call your doctor or poison control center right away.

Your doctor will check your heart, do regular blood tests and take bone marrow samples during treatment with TASIGNA. These are done to check for side effects with TASIGNA and to see how well TASIGNA is working for you. Your doctor should check your blood to monitor the amount of blood cells (white blood cells, red blood cells, and platelets) during treatment. These should be checked every two weeks for the first two months and then monthly thereafter, or as considered necessary by your doctor.

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

Please see accompanying patient information, including **Boxed WARNING**, and the TASIGNA Medication Guide you received with your prescription.

Indication

GLEEVEC® (imatinib mesylate) tablets are indicated for the treatment of newly diagnosed adult patients with Philadelphia chromosome–positive chronic myeloid leukemia (Ph+ CML) in chronic phase. Follow up is limited to 5 years.

GLEEVEC is also indicated for the treatment of patients with Philadelphia chromosome–positive chronic myeloid leukemia (Ph+ CML) in blast crisis, accelerated phase, or in chronic phase after failure of interferon-alpha therapy.

Who should NOT take GLEEVEC

- Women who are or could be pregnant. Fetal harm can occur when administered to a pregnant woman, therefore, women should not become pregnant, as well as be advised of the potential risk to the unborn child if GLEEVEC is used during pregnancy
- Women who are breast-feeding, because of the potential for serious adverse reactions in nursing infants
- Sexually active females should use adequate contraception while taking GLEEVEC

Be sure to talk to your doctor and/or nurse about these issues before taking GLEEVEC.

Important Safety Information

The following serious side effects have been reported in patients taking GLEEVEC:

- Severe fluid retention, which can be seen in swelling around the eyes or swelling of the lower legs, lungs and heart
- Low levels of certain blood cells
- Heart failure
- Liver problems
- Muscle or bone pain
- Abnormal bleeding (including gastrointestinal bleeding)
- Skin blistering
- Low levels of thyroid hormone

Your doctor will check you closely for any side effects to stop more serious complications from occurring. Patients with heart disease or risk factors for heart failure should also be monitored carefully.

GLEEVEC is sometimes associated with stomach or intestinal irritation.

- GLEEVEC should be taken with food and a large glass of water to minimize this problem
- There have been rare reports, including deaths, of stomach or intestinal perforation

Common side effects of GLEEVEC

A majority of patients with Ph+ CML experience side effects at some time. Most side effects are mild to moderate in severity. Some common side effects you may experience include:

- Fluid retention
- Vomiting
- Muscle cramps
- Muscle or bone pain
- Diarrhea
- Fatigue
- Nausea
- Rash
- Abdominal pain
- Hemorrhage (abnormal bleeding)

Some mild to moderate side effects can be managed with the help of other medicines and advice from your doctor. However, in some cases, your dose of GLEEVEC may be stopped for a while or may be changed.

Be sure to tell your doctor and/or nurse if you have any side effects during GLEEVEC therapy. Some signs or symptoms of side effects include sudden weight gain, fatigue, fever, shortness of breath, blood in stools or yellowing of the skin or eyes. Also tell your doctor if you have a history of heart disease or risk factors for heart disease.

Talk to your doctor and/or nurse about other medications you may be taking. Taking GLEEVEC with medicines such as ketoconazole; Tylenol® (acetaminophen); Coumadin® (warfarin); rifampin, St. John's wort (*hypericum perforatum*); erythromycin, Dilantin® (phenytoin), and Zocor® (simvastatin) may have an effect on how these drugs work, and these drugs may affect how GLEEVEC works.

Patients should also avoid grapefruit juice and other foods that may have an effect on how GLEEVEC works. Tell your doctor if you are taking or plan on taking iron supplements.

Take GLEEVEC exactly as prescribed. Do not change your dose or stop taking GLEEVEC unless you are told to do so by your doctor. If you miss a dose, take your dose as soon as possible, unless it is almost time for your next dose. In this case, your missed dose should not be taken. A double dose should not be taken to make up for any missed dose. You should take GLEEVEC with a meal and a large glass of water.

Are you *eligible* to participate in My CML Circle Co-Pay Assistance Program?

- If you are starting treatment with or currently taking GLEEVEC or TASIGNA for Ph+ CML **AND**
- You have private insurance or are cash-paying
- You make regular copayments for GLEEVEC or TASIGNA at your retail, specialty, or mail-order pharmacy

Who is *not eligible* to participate in My CML Circle Co-Pay Assistance Program?

- Patients whose payments for prescriptions may be made in whole or in part under federal or state healthcare programs, including, but not limited to, Medicare or Medicaid
- Residents of the state of Massachusetts

Enroll and participate in My CML Circle Co-Pay Assistance Program—it's fast, free, and easy

- You can enroll by calling toll-free at **1-877-966-2745**, or by visiting **www.mycmlcircle.com**, and you will be mailed a co-pay assistance card and welcome materials.

Please direct Ph+ CML patients starting or currently receiving GLEEVEC or TASIGNA to 1-877-966-2745 to enroll in My CML Circle Co-Pay Assistance Program!

Limitations: The My CML Circle Co-Pay Assistance Program co-pay card is not valid for prescriptions for which payment may be made in whole or in part under federal or state healthcare programs, including but not limited to Medicare or Medicaid, or for residents of Massachusetts. Not all patients will receive the specified total off their prescriptions. Total value of card is determined by applicable patient co-pay. Void where prohibited by law, taxed, or restricted. Void outside the USA.

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