GLEEVEC® (imatinib mesylate)

PATIENT RESOURCES

Ph+ CML Doctor Discussion Guide

Talking with your doctor about Ph+ CML and its treatment

When you have Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML), it's important to take an active role in your care. You will likely have many questions and may, at times, feel overwhelmed by all of the information.

Your doctor wants to help. But in many doctor appointments, there’s a lot to cover—and not a lot of time. So it’s important to go in prepared in order to get the most out of each visit. This guide can help. It's designed to help you prioritize key questions to ask your doctor at each step.

Print out this list and circle your top questions ahead of each visit to help ensure an informed conversation with your doctor.

Understanding Ph+ CML

• What is Ph+ CML and what causes it?
• What are the symptoms and risks of Ph+ CML?
• What are the tests used to diagnose Ph+ CML and determine how advanced the disease is?
• What are the different phases of Ph+ CML, and what do they mean?

Important Information

GLEEVEC® (imatinib mesylate) is available only by prescription.

GLEEVEC tablets are indicated for:

• Newly diagnosed adult and pediatric patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in the chronic phase
• Patients with Ph+ CML in blast crisis (BC), accelerated phase (AP), or in the chronic phase (CP) after failure of interferon-alpha therapy

Important Safety Information

Who Should NOT Take GLEEVEC

• Women who are or could be pregnant. Harm to the unborn child can occur when administered to a pregnant woman. Therefore, women should not become pregnant and should be advised of the potential risk to the unborn child if GLEEVEC is used during pregnancy. Sexually active females should use effective
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• What should I do if I experience side effects while taking GLEEVEC?
• What else do I need to know before taking GLEEVEC?
• What else can I do to help manage my Ph+ CML?

Getting support while taking GLEEVEC
• How can I work best with you and the rest of my health care team?
• Are there support programs available from the manufacturer of GLEEVEC, and how do I access those programs?
• How can I access the GLEEVEC $10 Co-Pay Card and find out if I am eligible?
• What other resources do you recommend for more support?

The GLEEVEC Patient Support program
What does GLEEVEC Patient Support offer?
The GLEEVEC Patient Support program is designed to be a comprehensive, no-cost addition to your treatment plan. It includes a variety of supportive resources.

Please note that the GLEEVEC Patient Support program does not replace the guidance, advice, or care that you receive from your doctor or primary health care provider.

Financial Support
Looking for ways to help access your medication? Let us help. You may qualify for a $10 co-pay* for a 30-day supply of GLEEVEC. Financial assistance may be available from other sources as well. Call 1-866-GLEEVEC (453-3832) or visit www.GLEEVEC.com to learn more.

Important Safety Information (cont)

birth control (methods that result in <1% pregnancy rates) while taking GLEEVEC and for 14 days after stopping GLEEVEC. Because of the potential for serious adverse reactions in breastfed infants, do not breastfeed during treatment with GLEEVEC and for 1 month after the last dose. Talk to your doctor right away if you think you are, or might be pregnant.

Warnings and Precautions
• GLEEVEC is often associated with edema (swelling) and serious fluid retention (holding water). It is important that patients be weighed and monitored regularly for signs and symptoms of serious fluid retention or unexpected weight gain. Patients experiencing unexpected, rapid weight gain should speak to their doctor about appropriate supportive care treatment. Studies have shown that edema tended to occur more often among patients who are 65 and older or those taking higher doses of GLEEVEC. If you experience severe fluid retention, your doctor may treat you with diuretics and may stop your GLEEVEC treatment until the fluid retention has been managed. Treatment can be resumed as appropriate depending on the initial severity of the event.

Please see Important Safety Information on pages 1-7, and full Prescribing Information here, which includes a more complete discussion of the risks associated with GLEEVEC.
Patient Counselors

Have questions about the GLEEVEC Patient Support program? Patient counselors are just a phone call away to answer questions you may have and help you navigate through the various offerings of the support program.

Educational Resources

Do you want to have the option to learn more about GLEEVEC? The GLEEVEC Patient Support program is the only place that provides you with exclusive tools, tips, guides, and a free patient resource kit.

Please call 1-866-GLEEVEC (453-3832) or visit www.GLEEVEC.com to learn more, and to register for this free support program.

Important Safety Information (cont)

- Cytopenias (reduction or lack of certain cell elements in blood circulation) have occurred. Your doctor will test your blood weekly for the first month, biweekly for the second month, and periodically thereafter. In most cases, your doctor will reduce or interrupt your GLEEVEC therapy; in rare cases, if the cytopenia is severe, your doctor may discontinue treatment.
- Congestive heart failure (impaired ability of the heart to pump blood) and left ventricular dysfunction (impaired functioning of the left side of the heart) have been reported, particularly in patients with other health issues and risk factors. Patients with heart disease or risk factors for heart disease or history of renal failure will be monitored and treated for the condition.
- Severe liver problems (hepatotoxicity) may occur. Cases of fatal liver failure and severe liver injury requiring liver transplants have been reported with both short-term and long-term use of GLEEVEC. Your doctor will check your liver function before beginning treatment and continue to monitor liver function as needed. If you experience severe liver problems, your doctor may stop your treatment with GLEEVEC until the liver problem has been managed.

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Important Safety Information (cont)

- Bleeding may occur. Severe gastrointestinal (GI) bleeding has been reported in patients with Ph+ CML and KIT+ GIST. GI tumor sites may be the cause of this bleeding. GI perforation (small holes or tears in the wall of the stomach or intestine), in some cases fatal, has been reported.

- In patients with hypereosinophilic syndrome (a condition with increased eosinophils, which are a type of white blood cell), eg, HES, MDS/MPD, or ASM and heart involvement, cases of heart disease have been associated with the initiation of GLEEVEC therapy. Speak to your doctor regarding appropriate supportive care or discontinuing GLEEVEC.

- Skin reactions, such as fluid-filled blisters, have been reported with the use of GLEEVEC.

- Clinical cases of hypothyroidism (reduction in thyroid hormones) have been reported in patients taking levothyroxine replacement during treatment with GLEEVEC. Your doctor should closely monitor your thyroid hormone levels.

- GLEEVEC can cause harm to an unborn child when administered to a pregnant woman. Therefore, women should not become pregnant and should be advised of the potential risk to the unborn child if GLEEVEC is used during pregnancy. Sexually active females should use effective birth control (methods that result in <1% pregnancy rates) while taking GLEEVEC and for 14 days after stopping GLEEVEC. Because of the potential for serious adverse reactions in breastfed infants, do not breastfeed during treatment with GLEEVEC and for 1 month after the last dose. Talk to your doctor right away if you think you are, or might be pregnant.

- Growth retardation (slowing of growth) has been reported in children taking GLEEVEC. The long-term effects of extended treatment with GLEEVEC on growth in children are unknown. Growth retardation may be monitored in children receiving treatment.

- Cases of tumor lysis syndrome (TLS), which refers to an electrolyte disturbance caused by the breakdown of tumor cells, have been reported and can be life threatening in some instances. The patients at risk for TLS are those who have a higher number of tumor cells and whose tumors are fast growing before beginning therapy. Your doctor should monitor you closely and take appropriate precautions. Correction of clinically significant dehydration and treatment of high uric acid levels are recommended prior to initiation of GLEEVEC.

- Motor vehicle accidents involving patients receiving GLEEVEC have been reported. Patients should be advised that they may experience side effects such as dizziness, blurred vision, or drowsiness during treatment with GLEEVEC. Caution is recommended when driving a car or operating machinery.

- A decline in kidney function has been reported in patients receiving GLEEVEC. Your doctor will check your kidney function when you start taking GLEEVEC and during therapy. Tell your doctor before starting on GLEEVEC if you have a history of kidney problems, diabetes, high blood pressure, or congestive heart failure.

Additional Important Safety Information

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

- Severe fluid retention (holding water), which can cause swelling around the eyes or swelling of the lower legs, lungs, and heart; fatal in rare cases.
Important Safety Information (cont)

- Increased pressure in the heart or brain; fatal in rare cases
- Low levels of certain blood cells
- Heart failure
- Liver problems
- Hemorrhage (abnormal 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 (a small hole or tear).

If you are experiencing any of the above-mentioned side effects, please be sure to speak with your doctor immediately.

Common Side Effects of GLEEVEC

Almost all patients treated with GLEEVEC experience side effects at some time. Some common side effects that you may experience include:

- Fluid retention (holding water)
- Muscle cramps, pain, or bone pain
- Abdominal pain
- Anorexia (loss of appetite)
- Vomiting
- Diarrhea
- Decreased hemoglobin (decrease in blood cells which carry oxygen)
- Hemorrhage (abnormal bleeding)
- Nausea
- Fatigue
- Rash

If you are experiencing any of the above-mentioned side effects, please be sure to speak with your doctor immediately.

The severity of some side effects may be reduced with the help of other medicines and advice from your doctor, while others may require stopping GLEEVEC therapy for a while or changing the dose. However, in some cases, GLEEVEC therapy may need to be discontinued.
**Important Safety Information (cont)**

Tell your doctor if you have a history of heart disease or risk factors for heart disease or if you experience side effects, including fever, shortness of breath, blood in your stools, jaundice (yellowing of the skin and/or eyes), sudden weight gain, or symptoms of heart failure during therapy with GLEEVEC.

After the approval of GLEEVEC, the following adverse events have been reported in patients treated with GLEEVEC: compression of the heart due to increased fluid, swelling of the brain, GI perforation (holes in the stomach or intestine), and sudden lung failure. These events, including some fatalities, may or may not have been drug related.

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.

Do not take any other medications without talking to your doctor or pharmacist first, including over-the-counter medications such as Tylenol® (acetaminophen); herbal products (St. John’s wort, Hypericum perforatum); or prescription medications including Coumadin® (warfarin sodium); rifampin; erythromycin; metoprolol; ketoconazole; and Dilantin® (phenytoin). Taking these with GLEEVEC may affect how they work, or affect how GLEEVEC works.

You should also tell your doctor if you are taking or plan to take iron supplements. Patients should also avoid grapefruit juice and other foods that may affect how GLEEVEC works.

Tylenol (acetaminophen) is a registered trademark of McNeil Consumer & Specialty Pharmaceuticals, a division of McNeil PPC, Inc. Coumadin (warfarin sodium) is a registered trademark of Bristol-Myers Squibb Company. Dilantin (phenytoin) is a registered trademark of Parke-Davis, a division of Pfizer Inc.

Please see full Prescribing Information, which includes a more complete discussion of the risks associated with GLEEVEC.

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.