Questions to Ask the Doctor

For your next conversation with your loved one’s doctor, here’s a list of questions that you may want to assist in asking. Time is limited in a doctor visit. Making a list of questions ahead of time not only captures all of your concerns, but it helps to keep the conversation concise. If you need more time, make a separate appointment with the doctor to follow up—and remember to write down important details of the visit to ensure they’re not forgotten.

**Newly Diagnosed**
1. Where is the tumor located? How big is it?
2. How likely is this tumor to grow or spread quickly?
3. Has the tumor spread from where it was originally found?
4. What treatment choices are there?
5. What do you recommend and why?
6. What are the risks relative to benefits of the treatments you suggest?
7. How might treatment affect daily activities?
8. What are the chances the cancer will come back with these treatment plans?
9. How many patients with KIT+ GIST have you seen and/or treated?
10. Would you recommend consulting with a KIT+ GIST specialist? Who would that be?

**After Surgery**
1. Will there be aftereffects of surgery?
2. Will I need to change my diet?
3. How will the surgery affect my digestion?
4. How long will I experience fatigue following surgery?
5. How many days will I have to be in the hospital?
6. Is there anything in particular I can do to help with my recovery?
7. What is the likelihood that my tumor will return?

**Advanced KIT+ GIST**
1. What is the prognosis?
2. Is there a way to keep the cancer at bay?
3. How many cases of advanced KIT+ GIST have you treated?
4. Would you recommend consulting with a KIT+ GIST specialist? Who would that be?

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

Please see Important Safety Information on pages 2-5, and full Prescribing Information.
Important Information (cont)

• Adult patients with relapsed or refractory Ph+ acute lymphoblastic leukemia (Ph+ ALL)
• Pediatric patients with newly diagnosed Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) in combination with chemotherapy
• Adult patients with myelodysplastic/myeloproliferative diseases (MDS/MPD) associated with PDGFR (platelet-derived growth factor receptor) gene rearrangements as determined with an FDA-approved test
• Adult patients with aggressive systemic mastocytosis (ASM) without the D816V c-KIT mutation as determined with an FDA-approved test or with c-KIT mutational status unknown
• Adult patients with hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL) who have the FIP1L1-PDGFRα fusion kinase and for patients with HES and/or CEL who are FIP1L1-PDGFRα fusion kinase negative or unknown
• Adult patients with unresectable, recurrent, and/or metastatic dermatofibrosarcoma protuberans (DFSP)
• Patients with KIT (CD117)-positive gastrointestinal stromal tumors (GIST) that cannot be surgically removed and/or have spread to other parts of the body
• Adult patients after surgery who have had their KIT (CD117)-positive GIST completely removed

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 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
• 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
Important Safety Information (cont)

- 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.

- 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.

Please see Important Safety Information on pages 2-5, and full Prescribing Information.
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
- 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.

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.
Additional Important Safety Information (cont)

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. 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.