Get the most out of your Gleevec

Learn more about your Ph+ CML

and your treatment with Gleevec

gleevec®
(imatinib mesylate) tablets

Please see enclosed Full Prescribing Information.
Get to know Gleevec

Understanding your condition and your treatment

Your doctor has prescribed Gleevec® (imatinib mesylate) tablets to treat your Ph+ CML (Philadelphia chromosome-positive chronic myeloid leukemia). Gleevec is the #1 prescribed product* for the treatment of Ph+ CML indicated in:

- Newly diagnosed adult patients with Ph+ CML in chronic phase. Follow-up is limited to 5 years.
- Adult patients with Ph+ CML in blast crisis, in accelerated phase, or in chronic phase after failure of interferon-alpha therapy

Getting the most out of Gleevec

For the best possible results, you should follow your doctor’s instructions about taking Gleevec. In fact, this is so important we created this brochure to help you do just that.

On the following pages, you will find useful information about your condition and taking Gleevec properly. There are also practical tips to help you get the best results.

*SUPPORT: Join the Gleevec Reports patient program

Gleevec Reports

Novartis Oncology, the maker of Gleevec, would like to offer you even more information and support to help you get the most out of your treatment with Gleevec. Gleevec Reports is a free educational program designed specifically to meet the needs of people with Ph+ CML.

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Join Gleevec Reports today

Start getting the tools and information you need to get the most out of your treatment.

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Additional Resources

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What you need to know

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Ph+ CML: A treatable condition

Understanding Ph+ CML

Chronic myeloid leukemia, or CML, is a slowly progressing type of cancer of the blood and bone marrow. The bone marrow is the inner part of your bones where blood cells are made. When you have CML, your body makes too many abnormal white blood cells.

What causes Ph+ CML

Ph+ CML begins when there is an abnormal change in the DNA (genetic material) of a young white blood cell. In most cases, this change leads to the creation of an abnormal chromosome, called the Philadelphia, or Ph, chromosome.

The Ph chromosome makes an abnormal protein called Bcr-Abl. This protein tells your bone marrow to make too many immature white blood cells, also called blast cells. Over time, these Ph+ white blood cells start to crowd out normal cells. When this happens, Ph+ CML can be life threatening if left untreated.
Three phases of CML

### Chronic phase
- About 50% of newly diagnosed patients have no symptoms
- Some people do experience fatigue, pain, and a sense of feeling full
- Many patients remain in this phase for a number of years without progressing to the more advanced phases

### Accelerated phase
- Symptoms may include fatigue, bruising, fever, night sweats, infection, and bone and abdominal pain
- Symptoms that occurred in the chronic phase may get worse

### Blast crisis phase
- Symptoms may include fatigue, bleeding, fever, weight loss, and complications related to infection
- Symptoms experienced in earlier phases may get worse

Ph+CML is a very serious condition, but the good news is that it is also treatable.
GLEEVEC: Treating the underlying cause of Ph+ CML

How Gleevec works

Gleevec is designed to affect the underlying cause of Ph+ CML—the Ph+ chromosome.* As mentioned earlier, the Ph+ chromosome makes an abnormal protein called Bcr-Abl.

Gleevec works by blocking the signal of the abnormal Bcr-Abl protein. This protein tells your bone marrow to make too many immature white blood cells, also called blast cells. Blocking this signal may stop the production and growth of these abnormal cells. Once that happens, normal blood cells can grow again.

*Gleevec is also known to inhibit other proteins in the body that may affect non-CML-related cells. Individual results may vary.

Please see important safety information on pages 14 through 17.
A main goal of treatment with Gleevec is to eliminate the cause of Ph+ CML, that is, cells containing the Ph chromosome. That’s why it’s so important to take your Gleevec as prescribed. Gleevec blocks the Bcr-Abl signal. This may stop the production and growth of those abnormal cells.

If you are responding to Gleevec and stop taking Gleevec or take less than your doctor has prescribed, the signal may no longer be blocked. Then, the number of abnormal white cells could start growing again.

With Gleevec, fewer abnormal white blood cells may be produced

Abnormal white blood cell
DOSING: Getting the best possible results from your treatment

Convenient and easy dosing

Gleevec is a tablet you take by mouth, not an injection. Gleevec is available in 100- and 400-mg scored tablets. Your starting dose usually depends on your phase of Ph+ CML. Your doctor will recommend a starting dose to help you achieve the best possible results.

Make the most of your treatment

- **DO** take Gleevec exactly as prescribed by your doctor
- **DO** take Gleevec with a meal and a large glass of water
- **DO** tell your doctor if you have a history of heart disease or risk factors for heart disease
- **DO** tell your doctor if you have any side effects or questions
- **DO NOT** take any other medications, over-the-counter medications such as acetaminophen, vitamins, or herbal supplements while taking Gleevec—including medications or herbal supplements to manage your side effects—without talking with your doctor first
- **DO NOT** take Gleevec with grapefruit juice, and ask your doctor about medications and other foods that affect how Gleevec works
- **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
- **DO NOT** take a double dose to make up for any missed dose

Living with a chronic condition can be a challenge, but it can be manageable. Keep a positive attitude and your overall health in mind.

Please see important safety information on pages 14 through 17.
The importance of taking Gleevec properly

DO NOT take Gleevec if...

• You are pregnant or could be pregnant. Fetal harm can occur when administered to pregnant women, 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. Sexually active females should use adequate birth control while taking Gleevec.

• You are breast-feeding, because of the potential for serious adverse reactions in nursing infants.

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

**Tips to help you stay on track with your treatment**

- Take Gleevec with the same meal every day
- Use a pill box with sections for each day of the week
- Put a reminder card where you’ll see it
- Use a watch alarm or timer as a reminder to take Gleevec
- Enroll in the Gleevec Reports program for extra support

Properly following your doctor’s treatment plan is important. If you are responding to Gleevec and stop taking Gleevec, the Bcr-Abl signal may no longer be blocked and the Ph+ CML process could start again. This may result in lack or loss of response to treatment or in disease progression.
GOALS: Reaching treatment milestones

Keeping track of your treatment goals

Goals of treatment with Gleevec can include:

- Eliminate cells that contain the Ph+ chromosome (the underlying cause of Ph+ CML) or reduce their number as much as possible
- Return blood cells and bone marrow cells to their normal numbers and functions

The importance of regular testing

To make sure you have the best possible response and reach your treatment goals, your doctor will want to do some tests. In fact, regular testing is recommended for all Ph+ CML patients taking Gleevec. There are 3 main types of tests:

- Hematologic test
- Cytogenetic test
- Molecular test or PCR (polymerase chain reaction) test

Please see important safety information on pages 14 through 17.
Keeping track of your treatment

<table>
<thead>
<tr>
<th>Tests</th>
<th>What they measure</th>
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<tbody>
<tr>
<td><strong>Hematologic</strong></td>
<td>Total number of white blood cells in your body</td>
</tr>
<tr>
<td><strong>Cytogenetic</strong></td>
<td>How many cells in the blood or bone marrow still have the Ph chromosome</td>
</tr>
<tr>
<td><strong>Molecular (PCR)</strong></td>
<td>Identifies the presence of any Ph+ cells by detecting very small amounts of Bcr-Abl protein in your blood and bone marrow</td>
</tr>
</tbody>
</table>

**Staying on your treatment with Gleevec**

Patients may respond to Gleevec differently. They may get different results or take longer to get the same results. That’s one of the reasons it’s so important to stay with Gleevec and give it time to work.

Even if you have very good results with Gleevec—and many patients do—it’s important to keep taking it. A good result—even a complete cytogenetic or molecular response—doesn’t mean you are cured. It doesn’t mean the Ph+ cells are gone. You still need to take your Gleevec as directed.
MANAGING SIDE EFFECTS:
Follow your doctor’s instructions

If you experience side effects during Gleevec therapy, don’t be discouraged. Your doctor will probably be able to help you manage them without adjusting your dose. In some cases, your doctor might need to lower or stop your dose of Gleevec for a short time. In rare cases, your doctor may permanently discontinue treatment.

- Your doctor will weigh you regularly and watch for signs of fluid retention. Unexpected weight gain may be a sign of serious fluid retention
- Your doctor will also monitor your blood counts to watch for anemia, as well as test for liver function before the start of treatment, and as needed thereafter.

Do not adjust your dose of Gleevec on your own.
Take Gleevec every day, exactly as directed.

Please see important safety information on pages 14 through 17.
### Some possible side effects

<table>
<thead>
<tr>
<th>Possible side effect</th>
<th>What it feels like</th>
<th>How your doctor may manage it</th>
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</thead>
<tbody>
<tr>
<td>Swelling and fluid retention</td>
<td>Swollen legs or feet and swelling around the eyes. Fluid retention can appear as quick weight gain or swelling in your lower legs or other parts of your body. Fluid retention can be serious or even life-threatening</td>
<td>• Prescribe a topical steroid cream to reduce the swelling around your eyes&lt;br&gt;• Tell you to limit your salt intake&lt;br&gt;• Prescribe a diuretic (a medicine to help your body get rid of extra fluids)</td>
</tr>
<tr>
<td>Rash</td>
<td>Scaly skin; red itchy bumps on skin</td>
<td>• Recommend an over-the-counter antihistamine&lt;br&gt;• Prescribe a corticosteroid or stronger antihistamine</td>
</tr>
<tr>
<td>Nausea and vomiting</td>
<td>Feeling queasy or like you have to throw up You may also feel like you have indigestion</td>
<td>• Recommend taking Gleevec with a meal and a large glass of water (If you have been instructed not to take Gleevec with meals, contact your doctor before changing your dose to mealtimes.)&lt;br&gt;• Recommend over-the-counter medications&lt;br&gt;• If you are taking your Gleevec once a day, talk to your doctor about possibly dividing the dose in half and taking it twice a day</td>
</tr>
<tr>
<td>Muscle cramps</td>
<td>Pain or spasms in the legs, feet, or calves</td>
<td>• Recommend an over-the-counter pain reliever, like ibuprofen&lt;br&gt;• Recommend a prescription pain reliever</td>
</tr>
<tr>
<td>Muscle and bone pain</td>
<td>Whole-body ache; twitching or burning muscles</td>
<td>• Recommend an over-the-counter pain reliever, like ibuprofen&lt;br&gt;• Recommend a prescription pain reliever</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>More bowel movements; loose stools</td>
<td>• Recommend an over-the-counter medication</td>
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</table>
Important information
Gleevec is available only by 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 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 pregnant women, 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 birth control 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 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
- Skin blistering

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.

Please see important safety information on pages 14 through 17.
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.

**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
- Nausea
- Muscle cramps
- Fatigue
- Vomiting
- Muscle or bone pain
- Diarrhea
- Rash

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.

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.

Be sure to inform your doctor if you are or think you may be pregnant. You should not breast feed while taking Gleevec.

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); Coumadin® (warfarin sodium); rifampin; erythromycin; and Dilantin® (phenytoin). These may 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 known to inhibit CYP3A4 (a substance that controls drug reactions) that may affect how Gleevec works.
SAFETY:
Important product information

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

After Gleevec’s approval, the following adverse events have been reported: compression of the heart due to increased fluid, swelling of the brain, increased pressure in the brain, and swelling in the eye, in patients treated with Gleevec. These events, including some fatalities, may or may not have been drug related.

Please consult accompanying complete Prescribing Information.

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 important safety information on pages 14 through 17.
Warnings and precautions

- Gleevec can cause fetal harm when administered to a pregnant woman. Women should be aware of the potential harm to the fetus
- Edema (swelling) and severe fluid retention have occurred. Your doctor will weigh you regularly and manage unexpected weight gain by drug interruption and diuretics
- Cytopenias (reduction or lack of certain cell elements in blood circulation) such as anemia, have occurred. Your doctor will perform complete blood counts weekly for the first month, biweekly for the second month, and periodically thereafter. In most cases, your doctor will reduce or interrupt your Gleevec dosing; in rare cases your doctor may discontinue treatment
- Severe congestive heart failure and left ventricle dysfunction have been reported, particularly in patients with other health issues and risk factors. Patients with heart disease or risk factors will be monitored and treated for the condition
- Severe liver problems (hepatotoxicity) may occur. Your doctor will check your liver function before beginning treatment and continue to monitor liver function as needed
- Gastrointestinal (GI) bleeding has been reported in patients with newly diagnosed CML and with GIST. GI tumor sites may be the cause of this bleeding
- Gastrointestinal perforation (small holes or tears in the walls of the stomach or intestine), some fatal, have been reported
- In patients with certain conditions associated with high eosinophil levels (eg, HES, MDS/MPD and ASM), beginning Gleevec has been associated with cardiogenic shock/left ventricle dysfunction
- Skin reactions, such as fluid-filled blisters, have been reported with Gleevec use
- Long-term use may result in potential liver, kidney, and/or heart toxicities; immune system suppression may also result from long term use

Please see accompanying complete Prescribing Information
GLOSSARY: Helpful words to know

**Bcr-Abl protein:** The abnormal protein that causes Ph+ CML. It results from the abnormal Philadelphia chromosome. It drives the growth and multiplication of abnormal white blood cells in Ph+ CML.

**Bone marrow:** The spongy inner part of bones where blood cells are made.

**Cytogenetic response:** A treatment-induced decrease in leukemic cells containing the Ph+ chromosome. A complete cytogenetic response occurs when no Ph+ cells are found.

**Fluorescence in situ hybridization (FISH):** A type of cytogenetic test that your doctor may use to look for the Bcr-Abl protein. It can be done using either blood or bone marrow cells.

**Hematologic response:** A reduction in blood cell levels due to treatment. A complete hematologic response occurs when the number of all blood cells returns to normal levels.

**Karyotyping:** A type of cytogenetic test your doctor may use to examine cells in a bone marrow sample. It looks at all of the chromosomes and can detect the presence of the Ph+ chromosome and other genetic abnormalities.

**Molecular response:** A treatment-induced reduction or elimination of the abnormal Bcr-Abl protein in the bone marrow or blood. Molecular response is measured by polymerase chain reaction (PCR). A complete molecular response means the Bcr-Abl protein is no longer detected.

Please see important safety information on pages 14 through 17.
**Myeloid:** A type of white blood cell.

**Philadelphia (Ph) chromosome:** The abnormal chromosome that is responsible for the production of Bcr-Abl, the cause of Ph+ CML.

**Ph+ chronic myeloid leukemia:** A slowly progressing cancer that makes the body produce too many abnormal myeloid white blood cells. Ph+ CML is caused by the presence of the Ph chromosome.

**Polymerase chain reaction (PCR):** The most sensitive test your doctor can use to identify Ph+ CML in your blood or bone marrow. It measures the level of Bcr-Abl. It can detect 1 abnormal Ph+ cell in 1 million normal cells.

**Protein:** An essential component of all living cells.

**White blood cell:** Cells made by bone marrow that help the body fight infection and other diseases. In leukemia, the body makes too many of these cells, which do not function properly.
INFORMATION: Additional resources

Keeping track of your treatment

Primary Care Physician          Oncologist
Name: ________________________   Name: ________________________
Specialty: ____________________
Nurse: ________________________  Nurse: ________________________
Phone: ________________________  Phone: ________________________

Pharmacy Information
Name: ________________________
Phone: ________________________
Prescription Names & Numbers: ________________________

My Tests

Hematological Tests

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Cytogenetic Tests

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Molecular Tests

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INFORMATION/SUPPORT

Get the most out of Gleevec.

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Additional resources

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**Cancer Care**
800-813-HOPE (800-813-4673)
www.cancercare.org

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

**The National Cancer Institute's Cancer Information Service**
800-4-CANCER (800-422-6237)
TTY: 800-332-8615
www.cancer.gov

For more information, call the Gleevec Hotline at 1-877-GLEEVEC (1-877-453-3832) or visit www.gleevec.com.