

## Answering your questions on Chronic Myeloid Leukaemia (CML)

# Your guide to understanding CML and Glivec® (imatinib) treatment

The information in this booklet is designed to help you understand chronic myeloid leukaemia (CML) and Glivec, the treatment your doctor has prescribed.

Understanding your disease and its treatment, and knowing what to expect, are important. You are sure to have many questions so, as well as reading this booklet, talk to your doctor about how you feel and any problems you may experience.

Remember:  
Medicines only  
work in people  
who take them



It is also vital that you continue to take Glivec every day for as long as your doctor prescribes it, even when you feel well. Glivec specifically targets the abnormality that causes CML and, like any medicine, it can only be effective if you continue to take it. Regular appointments with your doctor are important to make sure the treatment is working.

You may also want to contact other people with CML or support groups dedicated to helping people with cancer, and their families. Contact details are provided at the end of this booklet.

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# What is Leukaemia and Chronic Myeloid Leukaemia?



**Leukaemia** is a type of cancer of the blood and bone marrow - the spongy tissue inside bones, where blood cells develop. As a result of the disease, the body produces too many white blood cells, most of which are abnormal.

Chronic Myeloid Leukaemia (CML) is one type of leukaemia. '**Chronic**' means it is a slowly growing cancer that may take years to progress. '**Myeloid**' refers to the type of white blood cells being overproduced.

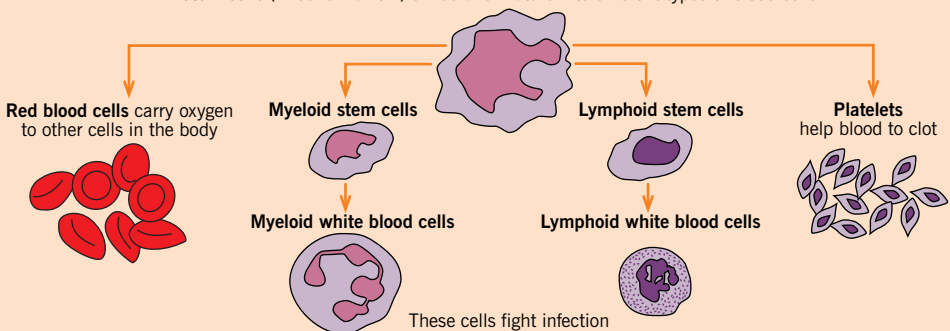
So **Chronic Myeloid Leukaemia** is a slowly progressing cancer that results in the body producing too many white blood cells of the myeloid type.

## Formation of blood cells

Bone marrow contains stem cells, which develop into three types of blood cells: red blood cells, white blood cells and platelets.

### Normal blood development

**Stem cells** (in bone marrow) divide and mature into different types of blood cells

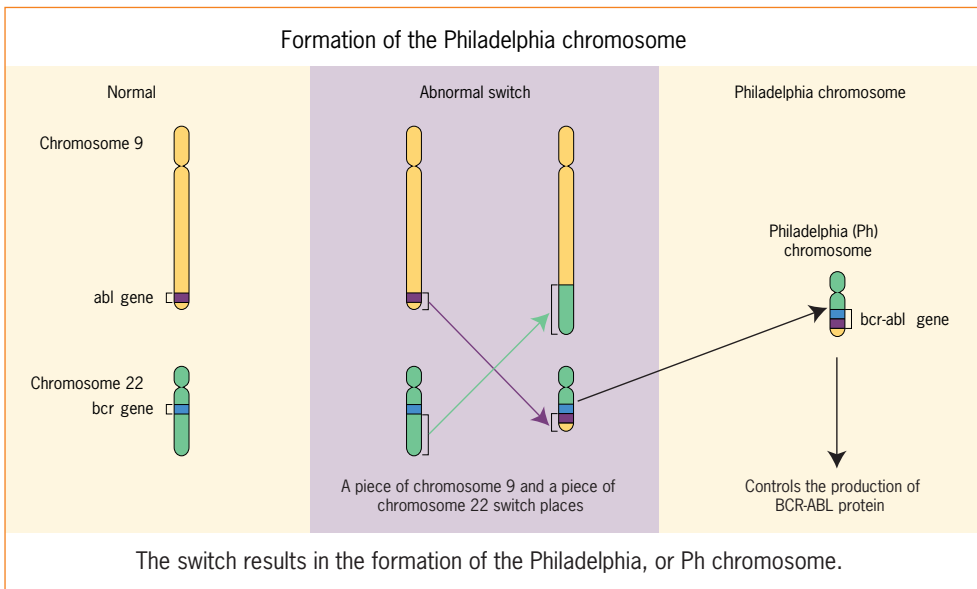


# What is Leukaemia and Chronic Myeloid Leukaemia?

People with CML have an abnormal chromosome in their myeloid stem cells and white blood cells

## How CML develops

People with CML have an abnormal chromosome in their myeloid stem cells and white blood cells. It is called the Philadelphia chromosome, and it is made up of small parts of two normal chromosomes switching places as shown in the diagram below. This abnormal Philadelphia chromosome initially develops in a single myeloid stem cell - the first 'leukaemic cell'. This cell then multiplies to form thousands and eventually millions of daughter leukaemic cells all containing the Philadelphia or Ph chromosome.





# How is CML treated?



There are a range of treatment options:

- stem cell transplantation
- drug therapies - such as chemotherapy, interferon alpha and Glivec
- a combination of the above

## **Stem cell transplantation (also called bone marrow transplantation)**

Stem cell transplantation firstly involves high dose chemotherapy, with or without radiotherapy, which kills all the cells in the bone marrow (normal stem cells as well as leukaemia cells). These cells are then replaced with a transfusion of normal stem cells which may be obtained from the bone marrow or blood stream.

### **A) Allogeneic stem cell transplantation**

This is where stem cells are donated from someone who has stem cells that are considered 'well matched' or compatible to the person's own. This could either be a family member or an unrelated donor.

### **B) Autologous stem cell transplantation ('autograft')**

This is where the person's own stem cells are collected ('harvested') when they have shown a good initial response to drug treatment. The stem cells are stored so that they can be re-infused if they are needed later on. This is still a relatively rare procedure and regarded as experimental.

# How is CML treated?*continued*

Glivec is a relatively new treatment for CML that specifically targets the genetic abnormality that causes CML.

## **Chemotherapy (i.e. hydroxyurea/busulfan)**

Chemotherapy is the use of cytotoxic (anti-cancer) drugs to destroy or control the leukaemia cells. Chemotherapies such as hydroxyurea and busulfan are usually used when drugs such as Glivec or interferon are not working as well as expected, or if a person is being prepared for transplantation.

They are used to help reduce the number of myeloid white cells in the blood and to treat some of the symptoms of CML, but have not been shown to prolong life.

Hydroxyurea is also sometimes used while a patient is waiting to begin treatment with Glivec, to help control the number of white blood cells in circulation.

## **Glivec® (imatinib)**

Glivec (also known in the United States as Gleevec®) is a relatively new treatment for CML that specifically targets the genetic abnormality that causes CML.

Comprehensive information on Glivec is provided in the following pages.



# All about Glivec



## How Glivec works

Glivec targets the cause of CML by blocking the action of the BCR-ABL protein. This protein interferes with the signal to the stem cells in the bone marrow to stop producing myeloid white blood cells.

In this way, Glivec can decrease the number of white blood cells being produced and cause the leukaemia cells with the Philadelphia chromosome to undergo cell death.

Because Glivec acts specifically on the abnormality that causes CML, it is less likely to affect normal cells than other drug therapies used to treat cancer.

## What Glivec treatment can achieve

The primary goal of Glivec therapy is to eliminate leukaemia cells with the Philadelphia chromosome.

Glivec has not been proven to 'cure' CML, but it has rapidly reduced the disease in many patients with chronic phase CML and has returned some patients with more advanced disease to the chronic phase.

It is important to remember that patients respond differently to therapy. How you respond to Glivec will depend on many factors, but your doctor has prescribed Glivec for you because he or she believes it is the right treatment for you.

To obtain the best chance of a good response to treatment, it is essential that Glivec tablets are taken continuously, exactly as prescribed by your doctor.

# All about Glivec *continued*



## Understanding your test results

A **Complete Haematological Response (CHR)** means that all blood cell types have returned to normal levels.

During a haematological response, the leukaemic cells containing the Philadelphia chromosome may still be present.

A **Major Cytogenetic Response (MCR)** means that the number of leukaemia cells with the Philadelphia chromosome has been considerably reduced i.e. the number of these cells has been reduced from levels as high as 100% at the start of treatment to levels between 1% and 35%.

A **Complete Cytogenetic Response (CCR)** means that none of the leukaemia cells with the Philadelphia chromosome are able to be detected by standard laboratory methods used to look at chromosomes within cells i.e. Philadelphia chromosome levels of 0%.

A **Major Molecular Response (MMR)** means that the levels of BCR-ABL have been reduced by at least 1,000 times from an average level seen in patients when they are first diagnosed with CML.

The test that is used to detect the level of BCR-ABL in blood or bone marrow is called **Polymerase Chain Reaction (PCR)**.

**PCR-negativity** is when the levels of BCR-ABL are reduced to such an extent that they cannot be detected using highly sensitive PCR measurements. This usually reflects a reduction in BCR-ABL of at least 10,000 times from an average level seen in patients when they are first diagnosed with CML.

## All about Glivec *continued*

To make sure your Glivec treatment can be effective, you have the important responsibility of taking it every day at the dose your doctor has prescribed.

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It is possible that, because of occasional side effects, you will want to take less of your medicine, or not take it at all. However, it is very important for you to continue taking Glivec as instructed, unless your doctor has told you to stop treatment or to reduce the dose.

### **Side effects that may occur**

In most people taking Glivec, side effects are mild to moderate. They often occur during the first month or two of treatment and may then decrease after this initial period.

The most common side effects are mild nausea, vomiting, diarrhoea, fatigue, headache, fluid retention, rash, muscle pains and cramps.

Each person's reaction to an anti-cancer drug is different. Some people may have very few side effects, while others may experience more. Tell your doctor about any side effects you have while taking Glivec. In most cases, side effects can be reduced with advice and treatments recommended by your doctor.

Important side effects are discussed in the following section.

# All about Glivec *continued*



## **Fluid retention**

A common side effect with Glivec therapy is fluid retention, also known as oedema. It is most common around the eyes but may also be seen in the ankles or legs.

Occasionally a build up of fluid may occur in other parts of the body, including the lungs, heart and abdomen. Your doctor will monitor you closely and weigh you on a regular basis to prevent complications from occurring.

If you notice any increase in weight or swelling anywhere in your body while taking Glivec, notify your doctor. You may be given a drug called a diuretic which can help reduce the amount of fluids in your body.

## **Fatigue and anaemia**

A feeling of fatigue and tiredness is very common when starting Glivec, and although this generally becomes less noticeable over time, some people do experience it for longer.

It is also common for people to develop anaemia (which means that the blood is less able to carry oxygen to the body, and is sometimes due to low levels of red blood cells or iron). This may add to the feeling of lethargy.

## **Diarrhoea**

If you experience diarrhoea during Glivec therapy, contact your doctor before taking any other drugs. Diarrhoea is usually mild and may be managed with over-the-counter medications.

## All about Glivec *continued*



If you experience side effects, please consult your doctor.

Do not stop taking Glivec or change the dose, unless your doctor tells you to.

### **Skin rash**

Some patients taking Glivec may develop a skin rash. If you notice any red patches, itchiness, or blistering, contact your doctor. You may be given an additional medication, such as an antihistamine or a topical corticosteroid cream, to reduce the rash.

If additional treatment does not help and the rash becomes severe, your doctor may find it necessary to interrupt your Glivec therapy.

### **Abdominal pain**

It is fairly common for people to develop abdominal pain while taking Glivec. If this is severe, contact your doctor.

### **Gastrointestinal (GI) bleeding**

Although this is relatively rare in people taking Glivec for CML, you should notify your doctor immediately if you observe any blood in your stools or if your stools look very dark in colour.

Other side effects not listed here may happen in some people. Some of these side effects can only be found by laboratory testing and your doctor will be taking blood tests periodically to monitor your status.

# All about Glivec *continued*



Good nutrition will help you cope better with CML and your treatment, and to feel better in yourself.

## Diet and lifestyle

Often simple changes to your diet and lifestyle can help reduce side effects.

- Eat a healthy, balanced diet with fresh fruit and vegetables. Good nutrition will help you cope better with CML and your treatment, and to feel better in yourself.
- To reduce nausea or diarrhoea, always take Glivec with a meal, and avoid foods that you know may upset your stomach such as spicy food.
- If it helps, take your Glivec with your main meal when you feel hungry and eat lighter meals at other times. You may prefer small frequent snacks rather than large meals.
- Eat slowly and chew well to help you digest your food better.
- Drink plenty of water and other fluids each day, to avoid becoming dehydrated.
- Get some light exercise, such as walking.



# Answers to your questions about Glivec



Do not reduce your dose of Glivec unless your doctor tells you to.

## **Q. Can I drink any alcohol while I am taking Glivec?**

- A.** Check with your doctor before consuming alcohol. Alcoholic beverages may usually be taken with Glivec, but the quantity should be limited to no more than one or two units per day. However, alcohol and Glivec are both processed by the liver. Your doctor may advise you to avoid alcohol if he or she is concerned about your liver health. In addition, if alcohol makes you feel nauseous while taking Glivec, it is best to avoid alcohol.

## **Q. Can I take Glivec if I am pregnant?**

- A.** No, you should not take Glivec if you are pregnant or planning to become pregnant, because Glivec may be harmful to your unborn baby. You must use contraception if there is a chance of you becoming pregnant, and tell your doctor immediately if you become pregnant while taking Glivec.

If it is necessary for you to take it during pregnancy, your doctor will discuss the risks and benefits involved.

## **Q. Can I take Glivec if I am breastfeeding?**

- A.** It is not known whether Glivec passes into breast milk, therefore breastfeeding is not recommended.



# Answers to your questions about Glivec



## **Q. Do I need to protect my skin from the sun?**

- A.** Glivec may cause your skin to be much more sensitive to sunlight than it normally is. Exposure to sunlight can cause skin rash, itching, redness or severe burning. When you are outdoors you should wear protective clothing and use at least a 15+ sunscreen. Do not use a sunlamp.

## **Q. What if I am unable to swallow tablets?**

- A.** Put the required tablet or tablets in a glass of water or apple juice (approximately 50ml for a 100mg tablet, and 200ml for a 400mg tablet). Stir with a spoon to completely disintegrate the tablet or tablets and immediately drink the whole contents of the glass.

# Where to get more information and support

## **Leukaemia Foundation of Australia**

Freecall: **1800 620 420**

Email: [info@leukaemia.com](mailto:info@leukaemia.com)

Website: [www.leukaemia.com](http://www.leukaemia.com)

- [www.novartis.com.au](http://www.novartis.com.au)

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