

Imatinib for treatment of chronic myeloid leukaemia

Haematology Department Patient Information Leaflet

Introduction

This leaflet is for people who are having a medication called imatinib for treatment of chronic myeloid leukaemia (CML).

Over the coming months, you will notice that there will be a change in the brand of imatinib that you receive. This leaflet will explain more about this and try to answer any questions you may have about this.

What is happening with imatinib?

In December 2016, the patent protection on the original brand of imatinib (Glivec®) for chronic myeloid leukaemia (CML) came to an end. (Glivec® is the Novartis brand of imatinib).

From January 2017, generic imatinib of the same composition and quality as Glivec® has become available from a number of different manufacturers at a much reduced price. For this reason, NHS England requires NHS trusts to start using generic imatinib for patients with CML.

What is a generic medicine?

A generic medicine is identical to a brand name drug in terms of dosage form, safety, strength, how it is taken and quality. Dosage form means how the drug molecules are delivered to the sites of action in the body.

Although generic drugs have the same chemicals as the branded versions, they are typically sold at much cheaper prices than the branded versions.

The use of generic medicines, for example, antibiotics, painkillers, heart medicines and cancer medicines; is very common in the NHS. Using generic medicines allows the NHS to make considerable savings that can be used to improve healthcare for all of us.

How can I be sure of the quality of generic imatinib?

The European Medicines Agency (EMA) is the authority that regulates the use of medicines across the whole of Europe including the UK (<http://www.ema.europa.eu>). There has been no change in that since the vote to leave the EU.

Health professionals and patients can be assured that EMA-approved generic medicines meet the same standards as the original branded drug. To gain EMA approval, a generic medicine must:

- contain the same active ingredients as the original drug (the inactive ingredients may vary);
- be identical in strength, dosage form, and route of administration (how the drug is given);
- be bioequivalent which means they have been assessed to be the same;
- meet the same batch requirements for identity, strength, purity, and quality; and
- be manufactured under the same strict standards of good manufacturing practice regulations required for the original product.

There is useful information from the EMA about generic medicines here:

http://www.ema.europa.eu/docs/en_GB/document_library/Medicine_QA/2009/11/WC500012382.pdf

The Medicines and Healthcare products Regulatory Agency (MHRA) is an executive agency of the Department of Health in the UK. MHRA is responsible for ensuring that medicines and medical devices work and are acceptably safe.

Evidence indicates that generic imatinib is as effective and has the same side effects as Glivec®. In addition, generic imatinib has been used in several countries for a few years without problems.

If I am already on Glivec® will I be switched to generic imatinib?

Yes, the whole of the NHS will switch over to generic imatinib.

Please note that your pills and the packaging containing them might look different.

Will I still be able to have other drugs if imatinib does not work for me?

Yes. Nilotinib and dasatinib are available if imatinib does not work. Bosutinib and ponatinib are also available for certain patients. This means that your doctor can still prescribe these for you.

Can I find out more?

You can find out more about generic imatinib:

Go to <http://www.ema.europa.eu/> and search for imatinib. This will tell you about the currently available generic versions of imatinib in Europe/UK and how they have been approved. At the moment, there are currently four versions of EMA-approved generic imatinib in addition to the original (Glivec®). There may be more in the future.

This link tells you about the regulation and safety monitoring of generic medicines:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/document_listing/document_listing_000335.jsp&mid=WC0b01ac0580514d5c

If you have any questions, or if there is anything you do not understand about this leaflet, please contact:

Haematology nurses Angela Young and Julie Rigby on 01384 456111 ext. 2453 (8am to 4pm, Monday to Friday)

Russells Hall Hospital switchboard number: 01384 456111

This leaflet can be downloaded or printed from:

<http://dudleygroup.nhs.uk/services-and-wards/haematology/>

If you have any feedback on this patient information leaflet, please email patient.information@dgh.nhs.uk

This leaflet can be made available in large print, audio version and in other languages, please call 0800 073 0510.

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此宣传单可提供大字版本、音频版本和其它语言版本，请拨打电话：0800 073 0510。

Ulotka dostępna jest również w dużym druku, wersji audio lub w innym języku. W tym celu zadzwoń pod numer 0800 073 0510.

ਇਹ ਪਰਚਾ ਵੱਡੇ ਅੱਖਰਾਂ, ਬੋਲ ਕੇ ਰੀਕਾਰਡ ਕੀਤਾ ਹੋਇਆ ਅਤੇ ਦੂਸਰੀਆਂ ਭਾਸ਼ਾਵਾਂ ਵਿਚ ਵੀ ਪ੍ਰਾਪਤ ਹੋ ਸਕਦਾ ਹੈ, 0800 073 0510 ਤੇ ਫੋਨ ਕਰੋ ਜੀ।

Aceasta brosură poate fi pusă la dispoziție tipărită cu caractere mari, versiune audio sau în alte limbi, pentru acest lucru va rugăm sunați la 0800 073 0510.

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