

Gilteritinib

Gilteritinib is a type of anti-cancer treatment called targeted therapy. The aim of this treatment is to control the cancer and its symptoms. Your doctor or nurse will be happy to answer any questions you have about your treatment. You may find it useful to refer to the booklet 'Chemotherapy, a guide' which gives general information on staying well during anti-cancer treatments.

Your treatment

Your doctor has prescribed for you a treatment called gilteritinib which belongs to a class of cancer medicines called protein kinase inhibitors. Gilteritinib is used to treat adults with acute myeloid leukaemia (AML), a cancer of certain white blood cells. Gilteritinib is used if AML is linked to an alteration of a gene called FLT3, and is given to patients whose disease has come back or has not improved after previous treatment.

This will be given in cycles, each cycle lasting 28 days.

Gilteritinib is taken by the mouth as tablets and must be taken at the same time every day.

You will have routine blood tests before the start of each cycle and during the cycle.

Occasionally we may not be able to go ahead with your treatment until your blood counts are back to a safe level. If this happens, your treatment may be delayed a week.

An ECG will also be done prior to therapy and as clinically indicated.

This treatment can have serious or possibly life-threatening side effects. It is very important that you report side effects straight away. Don't delay, if you feel unwell, please ring The Christie Hotline on **0161 446 3658**. The lines are open 24 hours a day.

Increased risk of serious infection

You are vulnerable to infection while you are having chemotherapy. Minor infections can become life-threatening in a matter of hours if left untreated. Symptoms of infection include fever, shivering, sweats, sore throat, diarrhoea, discomfort when passing urine, cough or breathlessness. We recommend that you use a thermometer so you can check your temperature. You can buy one from your local chemist.

If your temperature is 37.5°C or above, or below 36°C or you have symptoms of an infection, contact The Christie Hotline straight away



Possible side effects

Chemotherapy can cause many different side effects. Some are more likely to occur than others. We are all different, so we may get different side effects with varying severity. Most side effects are usually temporary, but in some rare cases they can be life-threatening. It is important to tell your hospital doctor or nurse about any side effects so they can be monitored and, where possible, treated.

Common side effects (more than 1 in 10)

- **Low white blood cell count**

There is a risk of infection and shingles.

- **Bruising or bleeding**

This treatment can reduce the production of platelets which help the blood to clot. Tell your doctor if you have unexplained bruising or bleeding, such as nosebleeds, bloodspots or rashes on the skin and bleeding gums. You may need a platelet infusion.

- **Anaemia (low number of red blood cells)**

While having this treatment you may become anaemic. This may make you feel tired and breathless. Let your doctor or nurse know if these symptoms are a problem. You may need a blood transfusion.

- **Gastrointestinal disturbance**

This treatment can cause constipation, diarrhoea, nausea, an increase or decrease in weight. It is important to drink plenty of fluid and maintain a balanced diet. Please report any of these symptoms to your nurse or doctor.

- **Lethargy**

This treatment may make you feel tired, short of breath or lacking in energy. It can be frustrating when you feel unable to cope with routine tasks. If you do feel tired, take rest when necessary. Gentle exercise such as walking can be beneficial.

- **Oedema**

Swelling due to fluid retention can be noticed, particularly in lower legs and ankles.

- **Low blood pressure**

You may have dizziness, nausea, feeling faint or have blurred vision.

- **Aches and pains**

Gilteritinib may cause muscular or joint aches and pains. A simple painkiller such as paracetamol may help with this. If you find that symptoms are persistent or unmanageable then speak to your doctor.

Uncommon side effects (less than 1 in 10)

- **Pericardial effusion**

Collection of fluid around the heart, which, if severe, can decrease the heart's ability to pump blood

- **Pericarditis**

Inflammation of the heart.

The following symptoms require medical attention, but are not an emergency. Contact your health care provider within 24 hours of noticing any of the following:

- Nausea (interferes with ability to eat and unrelieved with prescribed medication)
- Vomiting (vomiting more than 4-5 times in a 24 hour period)
- Diarrhoea (4-6 episodes in a 24-hour period)
- Constipation unrelieved by laxative use.
- Extreme fatigue (unable to carry on self-care activities) Mouth sores (painful redness, swelling and ulcers)
- Yellowing of the skin or eyes
- Swelling of the feet or ankles.
- Sudden weight gain.
- Signs of infection such as redness or swelling, pain on swallowing, coughing up mucus, or painful urination.
- Unable to eat or drink for 24 hours or have signs of dehydration: tiredness, thirst, dry mouth, dark and decreased amount of urine, or dizziness.

Serious and potentially life threatening side effects

In a small proportion of patients chemotherapy can result in very severe side effects which may rarely result in death. The team caring for you will discuss the risk of these side effects with you.

- **Differentiation syndrome**

Contact your doctor straight away if you have any of the following symptoms: fever, trouble breathing, rash, dizziness or lightheadedness, rapid weight gain, swelling of your arms or legs.

- **Posterior reversible encephalopathy syndrome (PRES) (Warning!)**

Contact your doctor straight away if you have a seizure, quickly worsening headache, confusion, or other vision problems.

- **Heart rhythm problems (QT prolongation) (Warning!)**

Contact your doctor straight away if you have a change in your heartbeat, or if you feel dizzy, lightheaded, or faint.

Late side effects

Some side effects may become evident only after a number of years. In reaching any decision with you about treatment, the potential benefit you receive from treatment will be weighed against the risks of serious long term side effects to the heart, lungs, kidneys and bone marrow. With some drugs there is also a small but definite risk of developing another cancer. If any of these problems specifically applies to you, the doctor will discuss these with you and note this on your consent form.

Sex, contraception and fertility

Pregnancy and breast feeding

Gilteritinib may harm your unborn baby and should not be used during pregnancy.

Women taking gilteritinib who are able to become pregnant should use an effective method of contraception during treatment with gilteritinib and for at least 6 months after stopping gilteritinib. If you use a hormonal contraceptive, you must also use a barrier method, such as a condom or a diaphragm. Men taking gilteritinib whose partners are able to become pregnant should use an effective method of contraception during treatment with gilteritinib and for at least 4 months after stopping the treatment.

It is not known if gilteritinib passes into your breast milk and could harm your baby. You should not breast-feed during treatment with gilteritinib and for at least 2 months after stopping the treatment.

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before taking this medicine.

Other medicines and Gilteritinib

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines. Gilteritinib may affect the way these medicines work, or these medicines may affect how gilteritinib works.

In particular, tell your doctor, pharmacist or nurse if you are taking any of the following medicines:

- medicines used to treat tuberculosis, such as rifampicin;
- medicines used to treat epilepsy, such as phenytoin;
- medicines used to treat fungal infections such as voriconazole, posaconazole or itraconazole;
- medicines used to treat bacterial infections such as erythromycin, clarithromycin or azithromycin;
- medicines used to treat high blood pressure (hypertension) such as captopril or carvedilol;
- medicines used to treat infections with the human immunodeficiency virus (HIV) such as ritonavir;
- medicines used to treat depression such as escitalopram, fluoxetine or sertraline;
- medicines used to treat heart problems, such as digoxin;
- medicines used to prevent blood clots, such as dabigatran etexilate;
- St. John's wort (also known as *Hypericum perforatum*), a herbal medicine used to treat depression.

If you normally take any of these medicines, your doctor might change it and prescribe a different medicine for you during your treatment with gilteritinib

Contacts

If you have any general questions or concerns about your treatment, please contact the Haematology team.

Lisa Jeffrey, Decima Govett or Emma Whitham, Haematology Clinical Nurse Specialists	0161 918 7962
Haematology day unit	0161 446 3924
General enquiries	0161 446 3000
For urgent advice ring The Christie Hotline	0161 446 3658 (24 hours).

Your consultant is:

Your hospital number is:

Your key worker is:

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For information and advice visit the cancer information centres at Withington, Oldham or Salford. Opening times can vary, please check before making a special journey.



Contact The Christie Hotline for
urgent support and specialist advice
The Christie Hotline: 0161 446 3658
Open 24 hours a day, 7 days a week