Your name:

....

Doctor's name:
(who prescribed Jyseleca)

....

Doctor's phone number:

....

The date you started Jyseleca:

....

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet.

You can report side effects directly via the national reporting system:

HPRA Pharmacovigilance Website:
www.hpra.ie or call **+353 1 6764971**

Any suspected adverse reactions to Jyseleca should be reported to Galapagos via email to **DrugSafety.UK.Ireland@glpg.com** or by telephone: **00800 7878 1345**

Please refer to the Jyseleca Patient Information Leaflet for further information. The PIL and additional Patient Alert Cards can be obtained from the HPRA website: **www.hpra.ie**

Patient Alert Card

Keep this card with you at all times.

Safety Information about Jyseleca®▼ (filgotinib) for patients.

This card contains important information for patients about the safety of Jyseleca. Please read the Patient Information Leaflet (PIL) for more information.

Keep this card with you at all times while taking Jyseleca and show this card to any healthcare provider involved in your care or treatment, for example a pharmacist or A&E doctor.

Further medical information can be obtained by emailing **medicalinfo@glpg.com** or by telephone on **00800 7878 1345**

Galápagos **IRE**

Infections

- Jyseleca may worsen an existing infection or increase your chances of getting a new infection. Tell your doctor straight away if you become ill or notice signs of infections, such as:

  - Fever or chills, shortness of breath, cough, feeling more tired than usual – these may be signs of pneumonia

  - Fever, sweating, weight loss or a cough that won't go away – these may be signs of tuberculosis (TB)

  - A painful skin rash with blisters – this may be a sign of shingles (herpes zoster)

- Before starting Jyseleca, tell your doctor if you have had shingles (herpes zoster) in the past as Jyseleca can allow it to come back.

- Before starting Jyseleca, ask your doctor if you should be tested for TB, including inactive infection.

- Tell your doctor if you have ever had or have recently been in close contact with a person with TB.

Blood clots in leg veins or lungs

- Tell your doctor straight away if you get symptoms of blood clots in your legs or lungs, such as a painful swollen leg, chest pain or shortness of breath.

Pregnancy, contraception and breast-feeding

- Jyseleca must not be taken during pregnancy:

  - Use effective contraception while taking Jyseleca and for 1 week after you take your last dose

  - If you become pregnant while taking Jyseleca, or think you may be pregnant, stop taking Jyseleca and talk to your doctor right away

  - If you are planning to become pregnant, talk to your doctor beforehand

- Do not breast-feed while you are taking Jyseleca.

Cholesterol

- High cholesterol is an important risk factor for heart disease. Whilst you are taking Jyseleca, your doctor will check your cholesterol levels. This will help decide if you need treatment to lower your cholesterol levels.

Vaccines

- You should not be given certain vaccines, called live vaccines, whilst or immediately prior to taking Jyseleca.

- Talk to your doctor or pharmacist about vaccines before starting Jyseleca. They may want to make sure you are up to date with your vaccinations.

Cancer and skin cancer

- Jyseleca may lead to an increased risk of cancer. Examine skin periodically and tell your doctor if you discover any new growth on your skin.

Heart disease

- Jyseleca may lead to an increased risk of certain heart diseases. Contact your doctor immediately if you experience chest pain or tightness (which may spread to arms, jaw, neck and back), shortness of breath, cold sweat, light headedness, sudden dizziness, weakness in arms and legs or slurred speech.

If you have any questions about your treatment, speak to your doctor.