

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



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, urinating more frequently than usual, pain or discomfort when urinating or back pain – these may be signs of urinary tract infection (UTI)
 - 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, ask your doctor if you should be tested for TB, including inactive infection
- Tell your doctor if you have recently been in close contact with a person with TB

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.

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

Vaccines

- You should not be given certain (live) vaccines (for example Zostavax used to prevent shingles) while 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

Effect on male fertility

It is possible that JYSELECA may lower sperm counts or affect sperm quality. The effects on the ability to father a child, and the reversibility of any potential effects, are unknown.

Speak to your doctor if you want to father a child now, or in the future.

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