

Patient Information Leaflet

Ireland

Galápagos



Jyseleca[®]
filgotinib



Package leaflet: Information for the patient

Jyseleca 100 mg film-coated tablets Jyseleca 200 mg film-coated tablets filgotinib

▼ 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. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Jyseleca is and what it is used for
2. What you need to know before you take Jyseleca
3. How to take Jyseleca
4. Possible side effects
5. How to store Jyseleca
6. Contents of the pack and other information

1. What Jyseleca is and what it is used for

Jyseleca contains the active substance filgotinib. It belongs to a group of medicines called Janus kinase inhibitors, which help reduce inflammation.

Rheumatoid arthritis

Jyseleca is used to treat adults with rheumatoid arthritis, an inflammatory disease of the joints. It can be used if previous therapy did not work well enough, or was not tolerated. Jyseleca can be used on its own, or together with another arthritis medicine, methotrexate.

Jyseleca reduces inflammation in your body. It helps to reduce pain, tiredness, stiffness and swelling in your joints, and it slows down damage to the bone and cartilage in the joints. These effects can help you to perform your normal daily activities, and improve your quality of life.

Ulcerative colitis

Jyseleca is used to treat adults with ulcerative colitis, an inflammatory disease of the bowel. It can be used if you did not respond well enough or did not tolerate previous therapy. It helps to reduce the signs and symptoms of ulcerative colitis and to reduce your need for steroids.

2. What you need to know before you take Jyseleca

Do not take Jyseleca

- **if you are allergic** to filgotinib or any of the other ingredients of this medicine (listed in section 6).
- **if you have active tuberculosis (TB).**

- **if you have an active serious infection** (see section “Warnings and precautions”).
- **if you are pregnant** or think you may be pregnant.

➔ If any of these apply to you, **do not take Jyseleca and tell your doctor immediately.**

Warnings and precautions

Talk to your doctor or pharmacist before taking Jyseleca:

- **if you have an infection**, or if you often get infections. Tell your doctor if you get symptoms such as fever, wounds, feeling more tired than usual or dental problems as these can be signs of infection. Jyseleca can reduce your body’s ability to fight infections and may make an existing infection worse or increase the chance of you getting a new infection. If you have diabetes or are aged 65 years or older you may have an increased chance of getting infections.
- **if you have ever had tuberculosis (TB)**, or have come into contact with somebody with TB. You may need tests to check for tuberculosis before and during treatment with Jyseleca.
- **if you have had a herpes zoster infection (shingles)** in the past, Jyseleca can allow it to come back. Tell your doctor if you get a painful skin rash with blisters during Jyseleca treatment as these can be signs of shingles.
- **if you have ever had hepatitis B or C.**
- **if you have or have had cancer, smoke or have smoked in the past**, because your doctor will discuss with you if Jyseleca is appropriate for you.
- **Non-melanoma skin cancer has been observed in patients taking Jyseleca.** Your doctor may recommend that you have regular skin examinations while taking Jyseleca. If new skin lesions appear during or after therapy or if existing lesions change appearance, tell your doctor.
- **if you recently had a vaccine**, or are due to have one. Certain types of vaccines (live vaccines) are not recommended while using Jyseleca. Talk to your doctor or pharmacist before you start Jyseleca. They may want to make sure that you are up to date with your vaccinations.
- **if you have, or have had, heart problems**, because your doctor will discuss with you if Jyseleca is appropriate for you.
- **if you have previously had blood clots** in the veins of your legs (deep vein thrombosis) or lungs (pulmonary embolism) or have an increased risk for developing this (for example: if you had a recent major surgery, if you use hormonal contraceptives\hormonal replacement therapy, if a coagulation defect is identified in you or your close relatives). Your doctor will discuss with you if Jyseleca is appropriate for you. Tell your doctor if you get sudden shortness of breath or difficulty breathing, chest pain or pain in upper back, swelling of the leg or arm, leg pain or tenderness, or redness or discoloration in the leg or arm as these can be signs of blood clots in the veins.

Elderly

Patients aged 65 years and older may be at increased risk of infections, heart attack and some types of cancer. Your doctor may decide that Jyseleca is not suitable for you.

Children and adolescents

Do not give this medicine to children and adolescents under 18 years of age because it has not been studied in this age group.

Other medicines and Jyseleca

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, especially if you use medicines that affect your immune system (such as ciclosporin or tacrolimus).

It is also very important to talk to your doctor or pharmacist if you are taking any of the following:

- medicines to treat heart failure, coronary disease or high blood pressure (such as diltiazem or carvedilol)
- the medicine fenofibrate (used to treat high cholesterol)

Pregnancy, contraception and breast-feeding

Pregnancy

Jyseleca must not be used in pregnancy. If you are pregnant, think you may be pregnant or if you are planning to have a baby, do not take this medicine. Talk to your doctor for advice.

Contraception

Be careful not to get pregnant while you are taking Jyseleca. You must use reliable contraception while you are taking Jyseleca, and for at least 1 week after you take your last dose of Jyseleca. If you do become pregnant while you are taking Jyseleca, stop taking the tablets and tell your doctor immediately.

Breast-feeding

Do not breast-feed while you are taking Jyseleca. It is not known whether the active substance passes into human breast milk.

Driving and using machines

Jyseleca can cause dizziness and vertigo. If you feel dizzy when taking Jyseleca, do not drive and do not use any tools or machines.

Jyseleca contains lactose

Each Jyseleca 100 mg film-coated tablet contains 76 mg of lactose, and each Jyseleca 200 mg film-coated tablet contains 152 mg of lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Jyseleca

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one 200 mg or 100 mg tablet once a day.

If you are aged 65 years of age or older with rheumatoid arthritis or if you have kidney problems, your doctor may recommend a dose of one 100 mg tablet once a day. Jyseleca is not recommended for you if you are over 75 years old with ulcerative colitis. Talk to your doctor if you have severe liver problems, as Jyseleca is not recommended for you.

Swallow your tablet with a glass of water. Do not split, crush, or chew the tablet before swallowing as it may change how much medicine gets into your body. You can take Jyseleca with food or between meals. Do not swallow the desiccant.

Take Jyseleca at the same time every day. This will help you to remember to take the tablets.

Your doctor may stop treatment temporarily or permanently if blood tests show a low white or red blood cell count.

If you take more Jyseleca than you should

If you take more tablets than you should, tell your doctor straight away.

If you forget to take Jyseleca

- If you miss a dose, take it as soon as you remember.
- If you have gone a whole day (24 hours) without taking a dose, just skip the missed dose and take a single dose at your usual time.
- Do not take a double dose to make up for a forgotten tablet.

If you stop taking Jyseleca

If you stop taking Jyseleca, tell your doctor straight away.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects

Talk to your doctor or get medical help straight away if you get any signs of serious infection such as:

- fever and symptoms of urinary tract infection (urinating more frequently than usual, pain or discomfort when urinating or back pain). Urinary tract infections are common (may affect up to 1 in 10 people), and some of these may be serious.
- lung infection (pneumonia): symptoms can include persistent cough, fever, shortness of breath, and tiredness. This is uncommon (may affect up to 1 in 100 people).
- shingles (herpes zoster): symptoms can include a painful skin rash with blisters. This is uncommon (may affect up to 1 in 100 people).
- Blood infection (sepsis): uncommon (may affect up to 1 in 100 people)

Other side effects

Talk to your doctor if you notice any of the following side effects:

Common

(may affect up to 1 in 10 people)

- throat and nose infections
- dizziness
- feeling sick (nausea)

Blood tests may show:

- a low number of white blood cells (lymphocytes).

Uncommon

(may affect up to 1 in 100 people)

- a spinning sensation (vertigo)

Blood tests may show:

- a low number of white blood cells (neutrophils)
- an increase in a muscle enzyme called creatine phosphokinase
- an increased level of blood fat (cholesterol).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:

United Kingdom (Northern Ireland)

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

Ireland

HPRA Pharmacovigilance

Website: www.hpra.ie

Malta

ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Jyseleca

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and bottle after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from moisture. Keep the bottle tightly closed. Do not use this medicine if you notice that the seal over the bottle opening is broken or missing.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Jyseleca contains

- The active substance is filgotinib. Each film-coated tablet contains 100 or 200 mg of filgotinib (as filgotinib maleate).
- The other ingredients are:
Tablet core: microcrystalline cellulose, lactose monohydrate, pregelatinised starch, colloidal silicon dioxide, fumaric acid, magnesium stearate
Film-coating: polyvinyl alcohol, titanium dioxide (E171), macrogol, talc, iron oxide yellow (E172), iron oxide red (E172)

What Jyseleca looks like and contents of the pack

Jyseleca 100 mg film-coated tablets are beige, 12 mm × 7 mm in size, capsule-shaped with “G” on one side and “100” on the other.

Jyseleca 200 mg film-coated tablets are beige, 17 mm × 8 mm in size, capsule-shaped with “G” on one side and “200” on the other.

Jyseleca 100 mg and 200 mg are available in bottles of 30 tablets and in packs made up of 3 bottles, each containing 30 tablets. Each bottle contains a silica gel desiccant that must be kept in the bottle to help protect your tablets. The silica gel desiccant is contained in a separate sachet or canister and should not be swallowed.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu>.

QR code to be included
www.jyseleca.eu