Package leaflet: Information for the patient
XELJANZ 11 mg prolonged-release tablets
tofacitinib

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.

In addition to this leaflet, your doctor will also give you a Patient Alert Card, which contains important safety information that you need to be aware of before you are given XELJANZ and during treatment with XELJANZ. Keep this Patient Alert Card with you.

What is in this leaflet

1. What XELJANZ is and what it is used for

XELJANZ is a medicine that contains the active substance tofacitinib.

XELJANZ is used for the treatment of the following inflammatory diseases:
- rheumatoid arthritis
- psoriatic arthritis
- ankylosing spondylitis

Rheumatoid arthritis
XELJANZ is used to treat adult patients with moderate to severe active rheumatoid arthritis, a long-term disease that mainly causes pain and swelling of your joints.

XELJANZ is used together with methotrexate when previous rheumatoid arthritis treatment was not sufficient or was not well tolerated. XELJANZ can also be taken on its own in those cases where methotrexate treatment is not tolerated or treatment with methotrexate is not advised.

XELJANZ has been shown to reduce pain and swelling of the joints and improve the ability to perform daily activities, when given on its own or together with methotrexate.

Psoriatic arthritis
XELJANZ is used to treat adult patients with a condition called psoriatic arthritis. This condition is an inflammatory disease of the joints, often accompanied by psoriasis. If you have active psoriatic arthritis you will be first given another medicine to treat your psoriatic arthritis. If you do not respond well enough or the medicine is not tolerated, you may be given XELJANZ to reduce the sign and symptoms of active psoriatic arthritis and improve the ability to perform daily activities.

XELJANZ is used together with methotrexate to treat adult patients with active psoriatic arthritis.

Ankylosing spondylitis

XELJANZ is used to treat a condition called ankylosing spondylitis. This condition is an inflammatory disease of the spine.

If you have ankylosing spondylitis, you may first be given other medicines. If you do not respond well enough to these medicines, you will be given XELJANZ. XELJANZ can help to reduce back pain, and improve physical function. These effects can ease your normal daily activities and so improve your quality of life.

2. What you need to know before you take XELJANZ

Do not take XELJANZ
- if you are allergic to tofacitinib or any of the other ingredients of this medicine (listed in section 6)
- if you have a severe infection such as bloodstream infection or active tuberculosis
- if you have been informed that you have severe liver problems, including cirrhosis (scarring of the liver)
- if you are pregnant or breast-feeding

If you are not sure regarding any of the information provided above, please contact your doctor.

Warnings and precautions
Talk to your doctor or pharmacist before taking XELJANZ:
- if you think you have an infection or have symptoms of an infection such as fever, sweating, chills, muscle aches, cough, shortness of breath, new phlegm or change in phlegm, weight loss, warm or red or painful skin or sores on your body, difficulty or pain when swallowing, diarrhoea or stomach pain, burning when you urinate or urinating more often than normal, feeling very tired
- if you have any condition that increases your chance of infection (e.g., diabetes, HIV/AIDS, or a weak immune system)
- if you have any kind of infection, are being treated for any infection, or if you have infections that keep coming back. Tell your doctor immediately if you feel unwell. XELJANZ can reduce your body's ability to respond to infections and may make an existing infection worse or increase the chance of getting a new infection
- if you have or have a history of tuberculosis or have been in close contact with someone with tuberculosis. Your doctor will test you for tuberculosis before starting XELJANZ and may retest during treatment
- if you have any chronic lung disease
- if you have liver problems
- if you have or had hepatitis B or hepatitis C (viruses that affect the liver). The virus may become active while you are taking XELJANZ. Your doctor may do blood tests for hepatitis before you start treatment with XELJANZ and while you are taking XELJANZ
- if you are 65 years of age and older, if you have ever had any type of cancer, and also if you are a current or past smoker. XELJANZ may increase your risk of certain cancers. White blood cell cancer, lung cancer and other cancers (such as breast, skin, prostate and pancreatic) have been reported in patients treated with XELJANZ. If you develop cancer while taking XELJANZ your doctor will review whether to stop XELJANZ treatment
- if you are at known risk of fractures, e.g., if you are 65 years of age and older, you are a female, or take corticosteroids (e.g., prednisone).
- Cases of non-melanoma skin cancer have been observed in patients taking XELJANZ. Your doctor may recommend that you have regular skin examinations while taking XELJANZ. If new skin lesions appear during or after therapy or if existing lesions change appearance, tell your doctor.
- if you have had diverticulitis (a type of inflammation of the large intestine) or ulcers in stomach or intestines (see section 4)
- if you have kidney problems
- if you are planning to get vaccinated, tell your doctor. Certain types of vaccines should not be given when taking XELJANZ. Before you start XELJANZ, you should be up to date with all

recommended vaccinations. Your doctor will decide whether you need to have herpes zoster vaccination
- if you have heart problems, high blood pressure, high cholesterol, and also if you are a current or past smoker
- if you have narrowing of the digestive tract tell your doctor as there have been rare reports of blockage in the digestive tract in patients taking other medicines using similar prolonged-release tablets
- when you take XELJANZ 11 mg prolonged-release tablets, you may see something in your stool that looks like a tablet. This is the empty shell from the prolonged-release tablet after the medicine has been absorbed by your body. This is to be expected and you should not be concerned

There have been reports of patients treated with XELJANZ who have developed blood clots in the lungs or veins. Your doctor will evaluate your risk to develop blood clots in the lungs or veins and determine if XELJANZ is appropriate for you. If you have already had problems on developing blood clots in lungs and veins or have an increased risk for developing this (for example: if you are seriously overweight, if you have cancer, heart problems, diabetes, experienced a heart attack (within previous 3 months), recent major surgery, if you use hormonal contraceptives\hormonal replacement therapy, if a coagulation defect is identified in you or your close relatives), if you are of older age, or if you smoke currently or in the past, your doctor may decide that XELJANZ is not suitable for you.

Talk to your doctor straight away if you develop 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 while taking XELJANZ, as these may be signs of a clot in the lungs or veins.

Talk to your doctor straight away if you experience acute changes to your eyesight (blurry vision, partial or complete loss of vision), as this may be a sign of blood clots in the eyes.

There have been reports of patients treated with XELJANZ who have had a heart problem, including heart attack. Your doctor will evaluate your risk to develop a heart problem and determine if XELJANZ is appropriate for you. Talk to your doctor straight away if you develop signs and symptoms of a heart attack including severe chest pain or tightness (that may spread to arms, jaw, neck, back), shortness of breath, cold sweat, light headedness or sudden dizziness.

<u>Additional monitoring tests</u>
Your doctor should perform blood tests before you start taking XELJANZ, and after 4 to 8 weeks of treatment and then every 3 months, to determine if you have a low white blood cell (neutrophil or lymphocyte) count, or a low red blood cell count (anaemia).

You should not receive XELJANZ if your white blood cell (neutrophil or lymphocyte) count or red blood cell count is too low. If needed, your doctor may interrupt your XELJANZ treatment to reduce the risk of infection (white blood cell counts) or anaemia (red blood cell counts).

Your doctor may also perform other tests, for example to check your blood cholesterol levels or monitor the health of your liver. Your doctor should test your cholesterol levels 8 weeks after you start receiving XELJANZ. Your doctor should perform liver tests periodically.

Elderly
There is a higher rate of infections, some of which may be serious, in patients 65 years of age and older. Tell your doctor as soon as you notice any signs or symptoms of infections.

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

Asian patients
There is a higher rate of shingles in Japanese and Korean patients. Tell your doctor if you notice any painful blisters on your skin.

You may also be at higher risk of certain lung problems. Tell your doctor if you notice any breathing difficulties.

Children and adolescents
XELJANZ is not recommended for use in children or adolescents under 18 years of age. The safety and benefits of XELJANZ in children or adolescents have not yet been established.

Other medicines and XELJANZ
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor if you have diabetes or are taking medicines to treat diabetes. Your doctor may decide if you need less anti-diabetic medicine while taking tofacitinib.

Some medicines should not be taken with XELJANZ. If taken with XELJANZ, they could alter the level of XELJANZ in your body, and the dose of XELJANZ may require adjustment. You should tell your doctor if you are using medicines that contain any of the following active substances:
- antibiotics such as rifampicin, used to treat bacterial infections
- fluconazole, ketoconazole, used to treat fungal infections

XELJANZ is not recommended for use with medicines that depress the immune system, including so-called targeted biologic (antibody) therapies, such as those that inhibit tumour necrosis factor, interleukin-17, interleukin-12/interleukin-23, anti-integrins, and strong chemical immunosuppressants including azathioprine, mercaptopurine, ciclosporin, and tacrolimus. Taking XELJANZ with these medicines may increase your risk of side effects including infection.

Serious infections and fractures may happen more often in people who also take corticosteroids (e.g., prednisone).

Pregnancy and breast-feeding
If you are a woman of childbearing age, you should use effective birth control during treatment with XELJANZ and for at least 4 weeks after the last dose.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. XELJANZ must not be used during pregnancy. Tell your doctor right away if you become pregnant while taking XELJANZ.

If you are taking XELJANZ and breast-feeding, you must stop breast-feeding until you talk to your doctor about stopping treatment with XELJANZ.

Driving and using machines
XELJANZ has no or limited effect on your ability to drive or use machines.

XELJANZ 11 mg prolonged-release tablet contains sorbitol
This medicine contains approximately 152 mg sorbitol in each prolonged-release tablet.

3. How to take XELJANZ

This medicine is provided to you and supervised by a specialised doctor who knows how to treat your condition.

Always take this medicine exactly as your doctor has told you, the recommended dose should not be exceeded. Check with your doctor or pharmacist if you are not sure.

Rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis
The recommended dose is one 11 mg prolonged-release tablet administered once daily.

Try to take your tablet (one 11 mg prolonged-release tablet) at the same time each day, e.g., morning or evening.

Swallow XELJANZ 11 mg prolonged-release tablets whole in order to ensure the entire dose is delivered correctly. Do not crush, split, or chew.

Your doctor may reduce the dose if you have liver or kidney problems or if you are prescribed certain other medicines. Your doctor may also stop treatment temporarily or permanently if blood tests show low white blood cell or red blood cell counts.

If you suffer from rheumatoid arthritis, psoriatic arthritis, or ankylosing spondylitis, your doctor may switch your tablets between XELJANZ 5 mg film-coated tablets twice daily and XELJANZ 11 mg prolonged-release tablets once daily. You can start the XELJANZ prolonged-release tablets once daily or XELJANZ film-coated tablets twice daily on the day following the last dose of either tablet. You should not switch between XELJANZ film-coated tablets and XELJANZ prolonged-release tablet unless instructed by your doctor.

XELJANZ is for oral use. You can take XELJANZ with or without food.

Ankylosing spondylitis

- Your doctor may decide to stop XELJANZ if XELJANZ does not work for you within 16 weeks.

If you take more XELJANZ than you should
If you take more prolonged-release tablets than you should, **immediately** tell your doctor or pharmacist.

If you forget to take XELJANZ
Do not take a double dose to make up for a forgotten 11 mg prolonged-release tablet. Take your next prolonged-release tablet at the usual time and continue as before.

If you stop taking XELJANZ
You should not stop taking XELJANZ without discussing this with your doctor.

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.

Some may be serious and need medical attention.

Possible serious side effects
In rare cases, infection may be life-threatening. Lung cancer, white blood cell cancer and heart attack have also been reported.

If you notice any of the following serious side effects you need to tell a doctor straight away.

Signs of serious infections (common) include

- fever and chills

- cough
- skin blisters
- stomach ache
- persistent headaches

Signs of ulcers or holes (perforations) in your stomach (uncommon) include
- fever
- stomach or abdominal pain
- blood in the stool
- unexplained changes in bowel habits

Holes in stomach or intestines happen most often in people who also take nonsteroidal anti-inflammatory drugs or corticosteroids (e.g., prednisone).

Signs of allergic reactions (unknown) include
- chest tightness
- wheezing
- severe dizziness or light-headedness
- swelling of the lips, tongue or throat
- hives (itching or skin rash)

Signs of blood clots in lungs or veins or eyes (uncommon: venous thromboembolism) include
- sudden shortness of breath or difficulty breathing
- chest pain or pain in upper back
- swelling of the leg or arm
- leg pain or tenderness
- redness or discoloration in the leg or arm
- acute changes in eyesight

Signs of a heart attack (uncommon) include
- severe chest pain or tightness (that may spread to arms, jaw, neck, back)
- shortness of breath
- cold sweat
- light headedness or sudden dizziness

Other side effects which have been observed with XELJANZ are listed below.

Common (may affect up to 1 in 10 people): lung infection (pneumonia and bronchitis), shingles (herpes zoster), infections of nose, throat or the windpipe (nasopharyngitis), influenza, sinusitis, urinary bladder infection (cystitis), sore throat (pharyngitis), increased muscle enzymes in the blood (sign of muscle problems), stomach (belly) pain (which may be from inflammation of the stomach lining), vomiting, diarrhoea, feeling sick (nausea), indigestion, low white blood cell counts, low red blood cell count (anaemia), swelling of the feet and hands, headache, high blood pressure (hypertension), cough, rash, acne.

Uncommon (may affect up to 1 in 100 people): lung cancer, tuberculosis, kidney infection, skin infection, herpes simplex or cold sores (oral herpes), blood creatinine increased (a possible sign of kidney problems), increased cholesterol (including increased LDL), fever, fatigue (tiredness), weight gain, dehydration, muscle strain, tendonitis, joint swelling, joint sprain, abnormal sensations, poor sleep, sinus congestion, shortness of breath or difficulty breathing, skin redness, itching, fatty liver, painful inflammation of small pockets in the lining of your intestine (diverticulitis), viral infections, viral infections affecting the gut, some types of skin cancers (non-melanoma-types).

Rare (may affect up to 1 in 1,000 people): blood infection (sepsis), lymphoma (white blood cell cancer), disseminated tuberculosis involving bones and other organs, other unusual infections, joint

infections, increased liver enzymes in the blood (sign of liver problems), pain in the muscles and joints.

Very rare (may affect up to 1 in 10,000 people): tuberculosis involving the brain and spinal cord, meningitis, infection of the soft tissue and fascia.

In general, fewer side effects were seen when XELJANZ was used alone than in combination with methotrexate in rheumatoid arthritis.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store XELJANZ

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 blister pack, bottle, or carton. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions.

Store in the original package in order to protect from moisture.

Do not use this medicine if you notice the tablets show visible signs of deterioration (for example, are broken or discoloured).

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 XELJANZ contains

- The active substance is tofacitinib.
- Each 11 mg prolonged-release tablet contains 11 mg of tofacitinib (as tofacitinib citrate).
- The other ingredients are sorbitol (E420) (see section 2 “XELJANZ 11 mg prolonged-release tablet contains sorbitol”), hydroxyethyl cellulose, copovidone, magnesium stearate, cellulose acetate, hydroxypropyl cellulose (E463), hypromellose (E464), titanium dioxide (E171), triacetin, red iron oxide (E172), shellac (E904), ammonium hydroxide (E527), propylene glycol (E1520) and black iron oxide (E172).

What XELJANZ looks like and contents of the pack

XELJANZ 11 mg prolonged-release tablet is pink and oval in appearance.
The tablets are provided in blisters containing 7 tablets. Each pack contains 28 or 91 tablets. The tablets are also available in bottles with silica gel desiccant containing 30 or 90 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Pfizer Limited

Ramsgate Road
Sandwich
Kent
CT13 9NJ

Manufacturer

Pfizer Manufacturing Deutschland GmbH
Betriebsstätte Freiburg
Mooswaldallee 1
79090 Freiburg
Germany

For any information about this medicine, please contact:
Medical Information, Pfizer Ltd, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS.
Telephone 01304 616161.

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