

XELJANZ[®]



[tofacitinib citrate]

RHEUMATOLOGY

This brochure has been produced for people who have been prescribed XELJANZ for the treatment of Rheumatoid Arthritis or Psoriatic Arthritis



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Introduction

Dear Patient,

Your doctor has prescribed you a medicine called XELJANZ for the treatment of rheumatoid arthritis or psoriatic arthritis.

This brochure contains information on how XELJANZ works and how to take it, as well as things to look out for before and during your treatment.

Please keep in mind that the information in this brochure is not a replacement for the advice given to you by your doctor. If you have any doubts or questions, please consult your doctor, nurse specialist or pharmacist.

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.

Before using XELJANZ, please review the package leaflet for this medicinal product.

- 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 of the package leaflet.

In addition to this leaflet, your doctor will also give you a Patient Alert Card, see page 39, 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.



A wide-angle photograph of the Cliffs of Moher in Ireland. The image shows a massive, dark, layered rock formation extending into the Atlantic Ocean. The sky is blue with scattered white clouds. In the foreground, there are rocky outcrops and some low-lying vegetation. A semi-transparent green box is overlaid on the lower part of the image, containing text.

What XELJANZ is and what it is used for

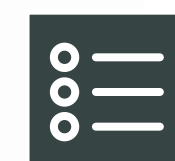
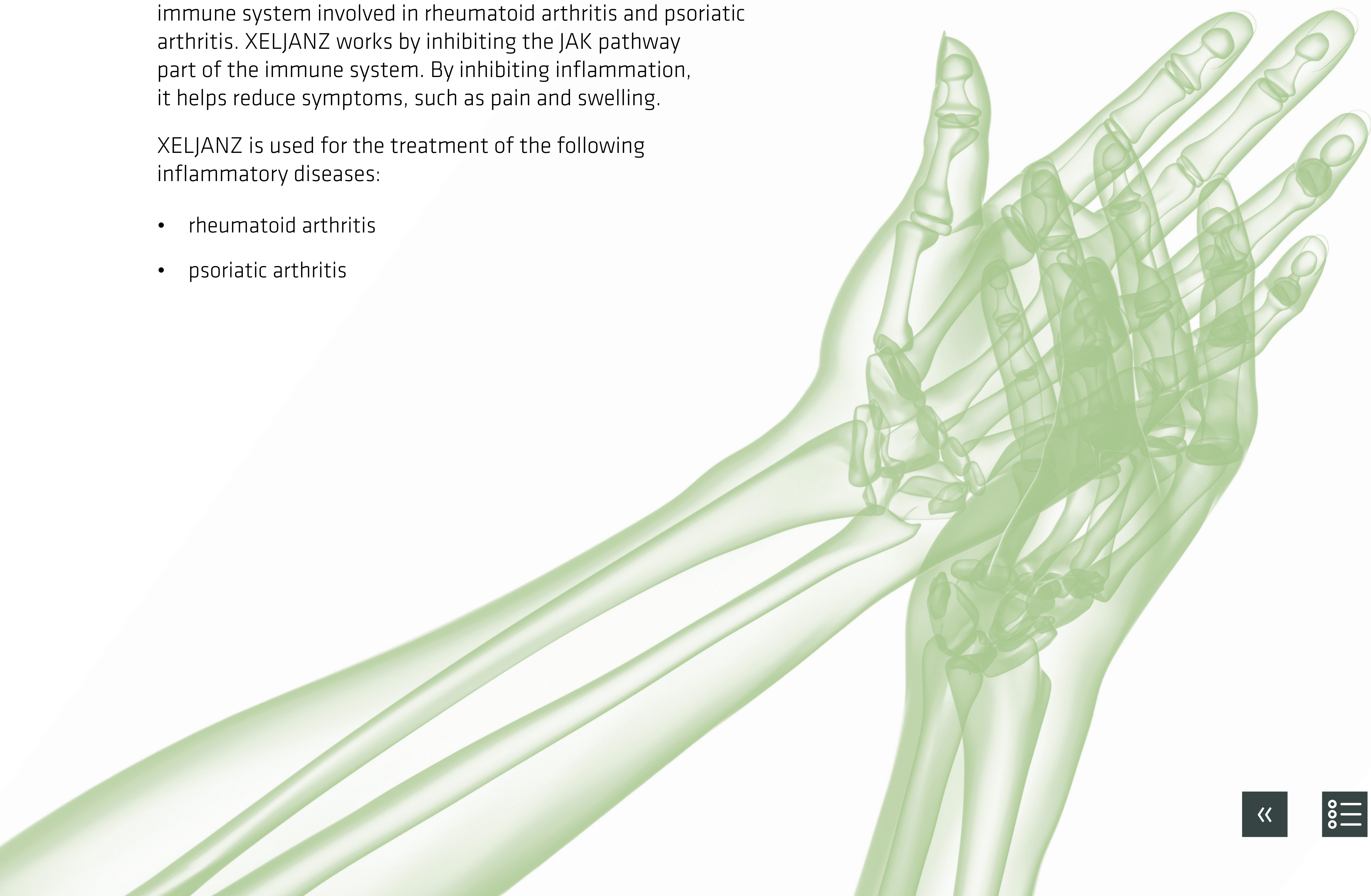


What XELJANZ is and what it is used for

XELJANZ is a medicine that contains the active substance tofacitinib. It is able to block the activation of parts of the immune system involved in rheumatoid arthritis and psoriatic arthritis. XELJANZ works by inhibiting the JAK pathway part of the immune system. By inhibiting inflammation, it helps reduce symptoms, such as pain and swelling.

XELJANZ is used for the treatment of the following inflammatory diseases:

- rheumatoid arthritis
- psoriatic arthritis



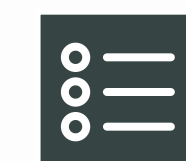
What is rheumatoid arthritis (RA)?^{1,2}

Rheumatoid arthritis (RA) is a chronic (long-term) disease that mainly causes pain and swelling of your joints. In RA the immune system, which normally protects you from infections, is activated against your own tissue due to an autoimmune response, resulting in inflammation.

XELJANZ is used to treat adult patients with moderate to severe active rheumatoid arthritis.

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.



What is psoriatic arthritis (PsA)?^{1,3}

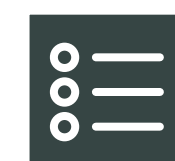


Psoriatic arthritis (PsA) is a form of chronic (long-term) inflammatory arthritis. It often affects people who have psoriasis, a disease that occurs when the immune system attacks the skin. Psoriasis can result in red and white scaly patches on the skin.

People with PsA may experience painful, stiff and swollen joints, though the symptoms vary from person to person. They may also include inflammation in the tendons, fingers or toes, and affect the skin.

XELJANZ is used to treat adult patients with psoriatic arthritis. 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.



A person wearing a teal sweater is holding a small white pill between their fingers and a piece of white paper in their other hand. The background is a blurred outdoor scene with greenery and a wooden fence.

What you need to know before you take XELJANZ

The tablet shown in this picture is for illustrative purposes only and does not represent XELJANZ.

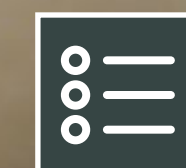


What you need to know before you take XELJANZ

Do not take XELJANZ:

- If you are allergic to tofacitinib or any of the other ingredients of this medicine (listed in section 6 of the package leaflet)
- 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 breastfeeding

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

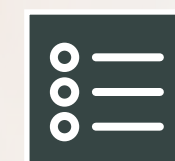


What you need to know before you take XELJANZ

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 older than 65 years, 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, melanoma, 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



What you need to know before you take XELJANZ

Talk to your doctor or pharmacist before taking XELJANZ:

- If you have had diverticulitis (a type of inflammation of the large intestine) or ulcers in stomach or intestines (see section 4 of the package leaflet)
- If you are at high risk of developing skin cancer, your doctor may recommend that you have regular skin examinations while taking XELJANZ
- 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 prolonged-release tablets similar to XELJANZ 11 mg
- 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.

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.

What you need to know before you take XELJANZ

Additional monitoring tests

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 in patients aged 65 years and older. Tell your doctor as soon as you notice any signs or symptoms of infections.

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 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

The safety and benefits of XELJANZ 5 mg have not yet been established in patients less than 2 years of age. XELJANZ 11 mg is not recommended for use in children or adolescents under 18 years of age.

Other medicines and XELJANZ

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

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 (taken by mouth) 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, ciclosporine, and tacrolimus. Taking XELJANZ with these medicines may increase your risk of side effects including infection.

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

What you need to know before you take XELJANZ

Pregnancy and breastfeeding

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 breastfeeding, 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 breastfeeding, you must stop breastfeeding 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 5 mg film-coated tablet contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

XELJANZ 5 mg film-coated tablet contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

XELJANZ 11 mg prolonged-release tablet contains sorbitol

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





How to take XELJANZ



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

- The recommended dose is 5 mg orally twice daily or 11 mg orally once daily.

Psoriatic arthritis

- The recommended dose is 5 mg orally twice daily or 11 mg orally once daily.

XELJANZ 5 mg twice daily

Try to take your tablet at the same time every day (one tablet in the morning and one tablet in the evening).

Xeljanz 5 mg tablets may be crushed and taken with water.

XELJANZ 11 mg prolonged-release

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.

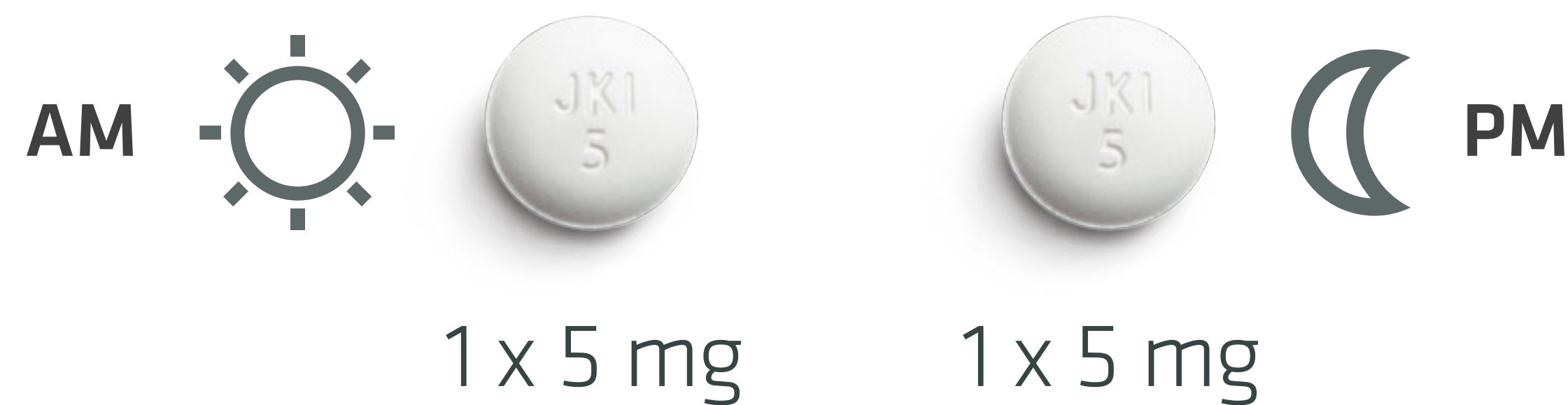
Your doctor may reduce the dose if you have liver or kidney problems or if you are prescribed certain other medicines. Your doctor may also stop treatment temporarily or permanently if blood tests show low white blood cell or red blood cell counts.

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



How to take XELJANZ

Recommended dose: 5 mg twice a day*



Recommended dose: 11 mg once daily*†



If you suffer from rheumatoid arthritis or psoriatic arthritis, 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 the XELJANZ film-coated tablet and the XELJANZ prolonged-release tablet unless instructed by your doctor.

If you take more XELJANZ than you should

If you take more 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 tablet. Take your next tablet at the usual time and continue as before.

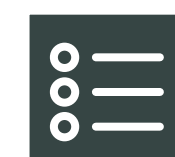
If you stop taking XELJANZ

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.

* Tablet does not represent actual size.

† The recommended dosing in RA and PsA is XELJANZ 5 mg twice daily **or** XELJANZ 11 mg prolonged-release once daily.¹





Possible side effects



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 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 (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

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

Possible side effects

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 red blood cell count (anaemia), fever, fatigue (tiredness), swelling of the feet and hands, headache, high blood pressure (hypertension), cough, rash.

Uncommon (may affect up to 1 in 100 people):

Lung cancer, tuberculosis, kidney infection, skin infection, herpes simplex or cold sores (oral herpes), low white blood cell counts, increased liver enzymes in the blood (sign of liver problems), blood creatinine increased (a possible sign of kidney problems), increased cholesterol (including increased LDL), weight gain, dehydration, muscle strain, pain in the muscles and joints, 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.

Very rare (may affect up to 1 in 10,000 people):

Tuberculosis involving the brain and spinal cord, meningitis.

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Ireland

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2;

Tel: +353 1 676 4971; Fax: +353 1 676 2517.

Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

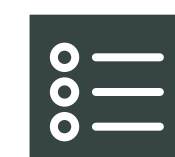


How to store XELJANZ



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 label. 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.





Contents of the pack and other information



Contents of the pack and other information

What XELJANZ 5 mg film-coated tablet contains

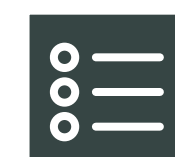
- The active substance is tofacitinib.
- Each 5 mg film-coated tablet contains 5 mg of tofacitinib (as tofacitinib citrate).
- The other ingredients are microcrystalline cellulose, lactose monohydrate (see section 2 of the package leaflet “XELJANZ contains lactose”), croscarmellose sodium (see section 2 of the package leaflet “XELJANZ contains sodium”), magnesium stearate, hypromellose (E464), titanium dioxide (E171), macrogol, and triacetin.

What XELJANZ 5 mg film-coated tablet looks like and contents of the pack

- XELJANZ 5 mg film-coated tablet is white and round in appearance.
- The tablets are provided in blisters containing 14 tablets. Each pack contains 56 tablets.



The pack shown does not represent the actual size.



Contents of the pack and other information

What XELJANZ 11 mg prolonged-release tablet contains

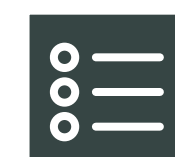
- The active substance is tofacitinib.
- Each 11 mg prolonged-release tablet contains 11 mg of tofacitinib (as tofacitinib citrate).
- The other ingredients are sorbitol (E420) (see section 2 of the package leaflet “XELJANZ 11 mg prolonged-release tablet contains sorbitol”), hydroxyethyl cellulose, copovidone, 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 11 mg prolonged-release tablet 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 tablets.



The pack shown does not represent the actual size.





Lifestyle tips

On the following pages we have some information that may be useful in the day-to-day management of RA and PsA. This includes healthy eating tips, advice for coping with stress and information to deal with fatigue.



Food and nutrition³⁻⁵

Healthy eating

Eating a healthy diet is important if you are living with arthritis. Although there is little evidence that specific foods have a direct effect on RA, a good diet can help you to maintain good health. If you have PsA, a good diet can help you to maintain a healthy weight, and to manage your cholesterol levels.

Foods to enjoy

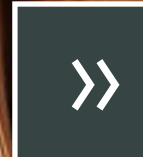
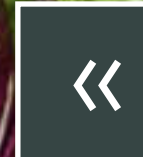
The important role of diet is to provide the nutrients you require and the energy you need to carry out daily exercise and activity.

Food should also be enjoyable.

As a general rule, a healthy diet contains plenty of fruit and vegetables.

Nuts, pulses (beans, chickpeas, lentils etc.) and grains are good sources of protein, and for non-vegetarians, meat and fish also provide protein and dairy products supply calcium and vitamins.

Eating a healthy and balanced diet is really important for people with rheumatic disease, as it is for everybody.



Diet and exercise^{3,4,6-8}

Foods to avoid

Processed convenience food tends to be less nutritious than food prepared at home. Such foods may also contain higher quantities of sugar and salt compared to food cooked at home.

Sugar is high in calories but low in nutrition, so some breakfast cereals, soft drinks and ready meals should be avoided. Too much salt can increase your blood pressure as well as your risk of heart disease and osteoporosis (weakening of your bones).

Some foods may also contain substances that interfere with medication. Your doctor or nurse will advise you, but you should also always read the package leaflet before taking any medication.

Weight control

Weight gain can be a problem because arthritis interferes with physical activity.

Extra weight puts extra stress on weight-bearing joints, from your backbone to your feet. That can be damaging whether you have arthritis or not. Everyone should pay attention to diet and exercise as a way of controlling their weight. If you are overweight, even a small amount of weight loss could make a big difference to your joints.

Staying active

Your doctor or physiotherapist will give you advice about staying active that is most appropriate for you. Different forms of activity might depend on which of your joints and muscles are affected as well as how severe the damage has become.

Staying active is important for people with arthritis because it can help ease stiffness, improve the movement in your joints and help keep your muscles strong.

Swimming allows you to stay active while taking weight off your joints. Cycling and walking are other simple forms of exercise that may help.



Caring for your skin⁹

Psoriasis and caring for your skin

Taking your XELJANZ medication can help manage PsA. However, there are also some lifestyle changes you can make to help manage your psoriasis day-to-day.

Moisturise your skin. This can help relieve dryness and itching. Speak with your dermatologist about moisturisers that may be suitable for your condition. Also, keep your skin clean.

Stay hydrated. Drinking plenty of water can help your skin to stay hydrated, especially in warmer weather.

Try and relax. Stress may make psoriasis worse. Try relaxation techniques, spend time with friends, listen to music, get plenty of rest and take time out for yourself. Ask your doctor if you need help managing stress or depression.

Speak to your doctor or dermatologist about the best way to manage your skin care.



Coping with stress^{10,11}

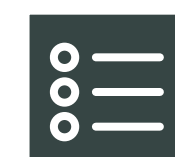
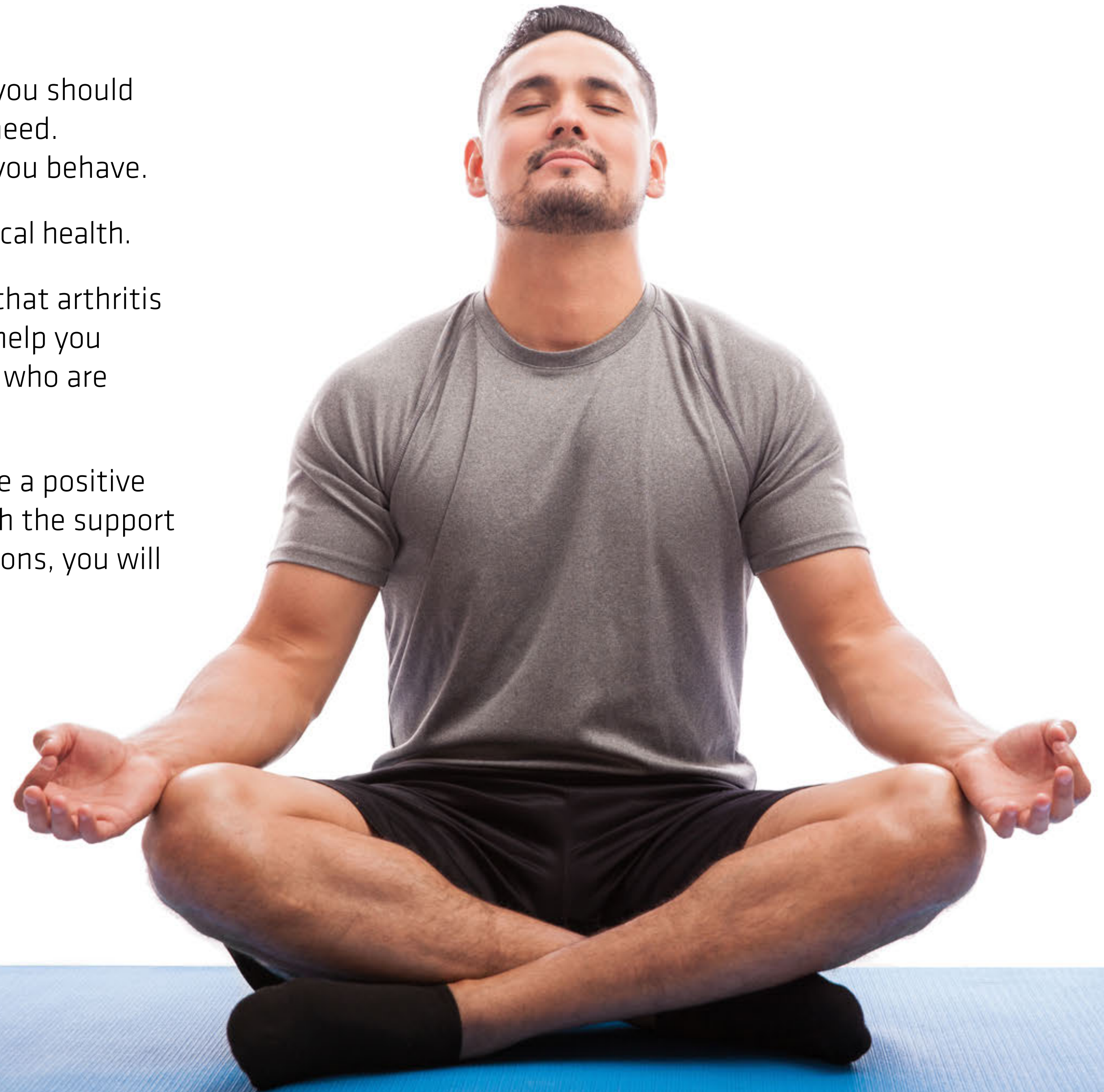
General wellbeing

Advice leaflets usually say what you should do and what you should not do. But how do you feel? Stress is the last thing you need. Stress can affect every aspect of your life, including how you behave.

Your emotional wellbeing is just as important as your physical health.

You can also find help to deal with the emotional effects that arthritis can have on your wellbeing. Your doctor is best placed to help you with emotional problems and will direct you to therapists who are professionally qualified.

If you can take control of your life with arthritis it can have a positive impact on your emotional and physical wellbeing, and with the support from your healthcare team, patient groups and organisations, you will be better equipped to live life to the full.



Fatigue¹²⁻¹⁵

Fatigue

One of the hardest parts of living with your disease can be the fatigue that often comes with it. It is different than the tiredness you can feel after a late night or a hard day at work. Fatigue is an ongoing feeling of exhaustion that can affect your quality of life.

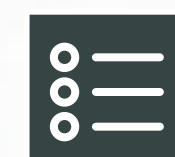
Resting when your body is tired can give your body time to recover and allow it to build its energy supplies back up again. You should also try to get into good sleep patterns to give yourself the best chance of a relaxing night's sleep. Going to bed at the same time every night, and taking the time to 'switch off' properly, may help.

Sleep

It may sound obvious, but getting a good night's sleep is one of the keys to managing fatigue. Sleep can also help ease pain. Studies suggest that people who sleep poorly have a lower pain threshold than people who sleep well. Fatigue and a lack of sleep can become a continuous circle: not getting enough sleep can lead to increased fatigue, pain and inflammation. This can, in turn, stop you from getting a good night's sleep.

Tips for getting a better nights sleep

- Take time out for a quiet rest rather than naps during the day.
- Avoid alcohol, caffeine and large meals just before bedtime.
- Try to stay active – exercise can fight fatigue and help improve your sleep.
- Go to bed and get up around the same time every day so your body gets into a pattern.
- Avoid watching TV or using a tablet at bedtime, and keep clutter and other distractions to a minimum. Make your bedroom a 'sleep-only zone'.
- If you can't get to sleep, get up and 'reset' your bedtime routine. Try reading or listening to music in another room until you feel ready to sleep.



Stopping smoking^{16,17}

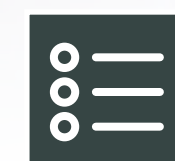
Smoking

Smoking can cause a range of health problems, including cancers and heart conditions. It is also a risk factor for RA and PsA, and may make your symptoms worse.

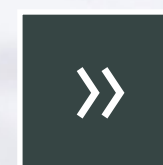
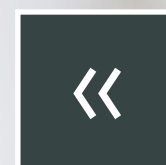
Smoking affects the immune system and reduces your body's ability to fight disease.

If you are a smoker, it is important to take steps to stop smoking.

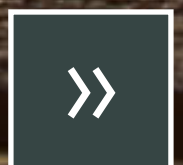
Your doctor or pharmacist will be able to offer extra advice and support to help you quit smoking.



Your emotional wellbeing is just as important as your physical health.¹¹



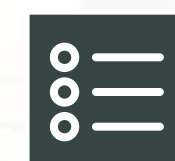
Sidekick Digital Care App



Sidekick Digital Care App

Do you believe your condition is always a step ahead of you?...We get it!

The **Sidekick Digital Care App** and the programme offered within it, could help you to improve your everyday life living with your condition, remind you to take your medication and empower you to take control of your own health.



Sidekick Digital Care App

Sidekick – Your Coaching Team for Rheumatoid Arthritis & Psoriatic Arthritis

Does your day-to-day life always revolve around the same questions?

- Why am I so tired?
- Have I taken my medication already?
- How do I deal with stress?
- Where can I quickly get a trustworthy answer to questions about my condition?

The Sidekick programme for patients with Rheumatoid Arthritis and Psoriatic Arthritis, supports and coaches you in many areas of everyday life – simply and practically in the Sidekick Digital Care App.

As well as supporting you with your medication plan, Sidekick also offers you support in the areas of nutrition, exercise and stress management.



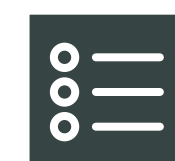
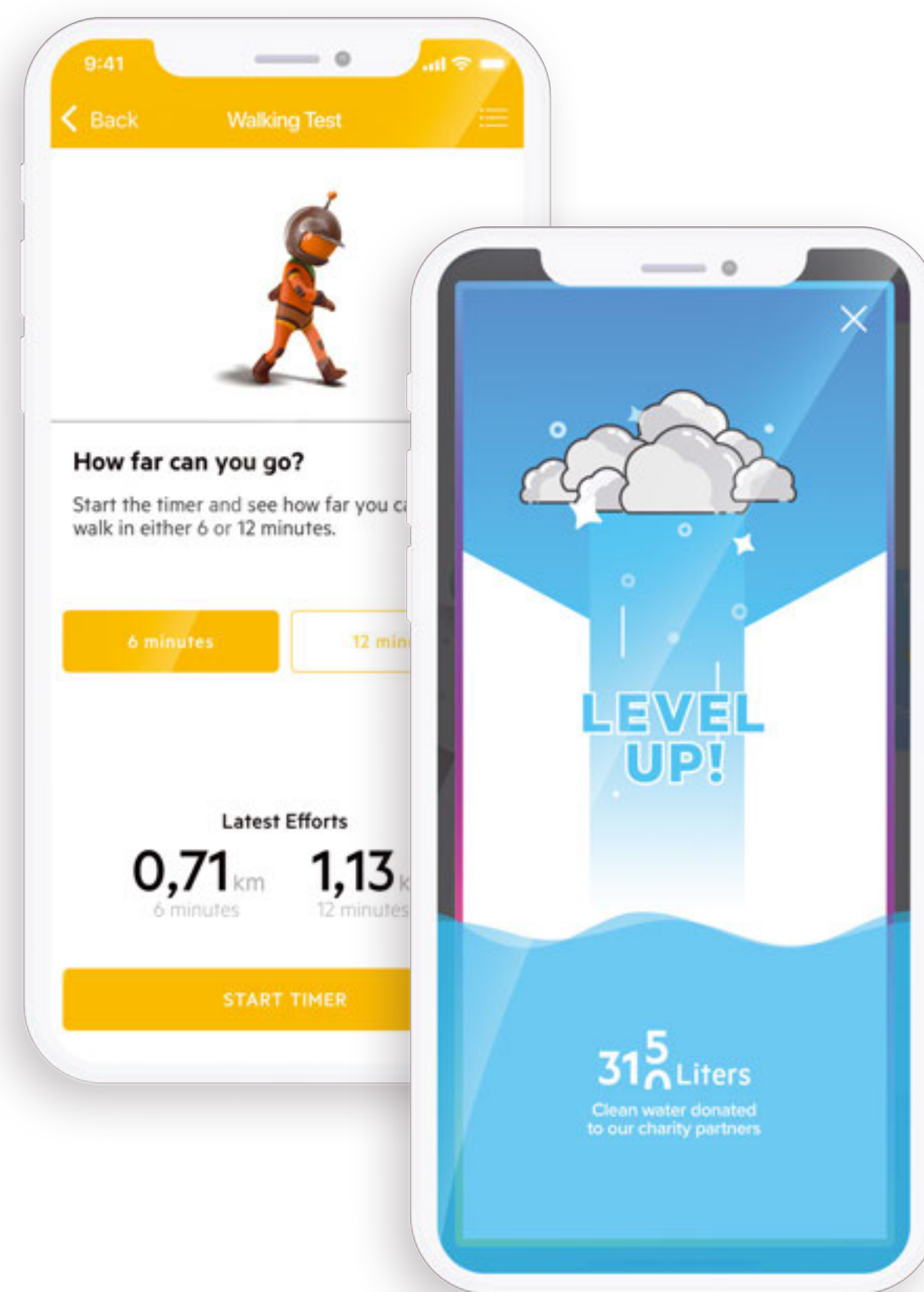
Sidekick Digital Care App

Level up with Sidekick!

Staying healthy with Sidekick is fun!

In addition to a focus on your wellbeing, you can also positively impact the wellbeing of others, in more disadvantaged parts of the world.

Points can be scored through various game like challenges within the app, each time you go up a level. Sidekick then convert your scored points into clean drinking water, that they donate to their charity partners.



Sidekick Digital Care App

How to scan the QR code

1. Open the camera app on your smart phone.
2. Point the camera at the QR code, so that the QR code is visible on the screen of your phone.
3. Once the camera reads the QR code, a notification will pop up on the screen that the QR code has been detected.
4. Tap the notification to open the link for the Sidekick Digital Care App.

Load your personal Sidekick Coaching Team now!

SCAN HERE to go to the
Sidekick programme for
Rheumatoid Arthritis



Developed by



SCAN HERE to go to the
Sidekick programme for
Psoriatic Arthritis



Supported by



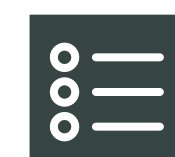
Sidekick Health is a Nordic digital therapeutics innovator that provides science-based, digital services designed to support patients.

Note: Pfizer has no influence over the function or content of the Sidekick Digital Care Application, or the programmes contained therein. Pfizer supports SidekickHealth financially, in the context of a collaboration to make the programmes therein available exclusively to patients within the Republic of Ireland.



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Patient Alert Card

PATIENT ALERT CARD

XELJANZ[®]▼ (tofacitinib citrate)

- This card contains important safety information that you need to be aware of before you start taking XELJANZ and during your treatment with XELJANZ. If you do not understand this information, please ask your doctor/ pharmacist to explain it to you.
 - Keep this card with you and show it to your healthcare provider, including any emergency staff, who may be treating you apart from your specialist. It's important you make them aware that you are taking XELJANZ to treat your condition.
 - See the XELJANZ patient information leaflet for more information. You should use XELJANZ following the information within the patient information leaflet.
- Tell your doctor or your pharmacist about ALL the medicines you take**, including prescription and non-prescription medicines, vitamins and herbal supplements.

Some medicines should not be taken with XELJANZ as they could alter the level of XELJANZ in your body and your dose may require adjustment. You should tell your doctor if you are using medicines that contain the following active substances:

- Antibiotics such as rifampicin, used to treat bacterial infections.
- Fluconazole and ketoconazole used to treat fungal infections.

There is a possibility that you may experience more side-effects when you are given XELJANZ and another medicine called methotrexate at the same time.

XELJANZ is not recommended for use with biologic DMARDs* for rheumatoid arthritis or psoriatic arthritis, biologics for ulcerative colitis, or with certain other medicines that depress your immune system (e.g., azathioprine, mercaptopurine, tacrolimus or ciclosporine). Taking XELJANZ with these medicines may increase your risk of immunosuppression and infection.

* DMARD=disease-modifying antirheumatic drug.

XELJANZ may increase your risk of getting infections, which can become serious if not treated. You may be at higher risk for infections if you are 65 years of age or older, have diabetes, chronic lung disease, or are taking corticosteroids. Your XELJANZ treatment may be stopped by your doctor.

Treatment with XELJANZ may increase your risk of non-melanoma skin cancer.

During treatment with XELJANZ

Tell your doctor **immediately** 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 discolouration in the leg or arm while taking XELJANZ, as these may be signs of a clot in the lungs or veins.
- Develop symptoms of an infection, such as fever, persistent cough, weight loss, or excessive tiredness.
- Develop any symptoms of herpes zoster, such as painful skin rash or blisters.
- Have been in close contact with a person with tuberculosis.
- Notice any new growth on the skin or any changes in existing moles or spots.
- Develop symptoms of interstitial lung disease, such as shortness of breath.
- Develop abdominal signs and symptoms such as stomach pain, abdominal pain, blood in your stool, or any change in your bowel habits with fever.
- Develop yellow skin, nausea or vomiting.
- Are due to receive any vaccine. You should not receive certain types of vaccines while taking XELJANZ.
- Become pregnant or plan on becoming pregnant. XELJANZ must not be used during pregnancy. Women of childbearing potential should be advised to use effective contraception during treatment with XELJANZ and for at least 4 weeks after the last dose.
- Women must not breastfeed while being treated with XELJANZ.

Other Information (please complete)

Patient's name: _____

Doctor's name: _____

Doctor's phone: _____

If you stop taking XELJANZ, keep this card with you for at least 2 months after taking the last dose of XELJANZ.

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. Any suspected adverse reactions may also be reported to Pfizer Medical Information on 1800 633 363.

XELJANZ[®]



[tofacitinib citrate]

▼ 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 of the package leaflet for how to report side effects.

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



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