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# Xeljanz

**Pronunciation:** *zel-jans*

**Generic name:** [tofacitinib](#)

**Brand names:** Xeljanz, Xeljanz XR, Xeljanz Oral Solution

**Dosage form:** oral tablet, extended-release tablet, oral solution

**Drug class:** [Antirheumatics](#)

Medically reviewed by [Carmen Pope, BPharm](#). Last updated on Aug 22, 2024.

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## What is Xeljanz?

**Xeljanz** (tofacitinib) is an oral Janus kinase (JAK) inhibitor that may be used alone or with other medications to **treat inflammatory and autoimmune conditions** such as rheumatoid arthritis, psoriatic arthritis, ulcerative colitis, ankylosing spondylitis, and polyarticular juvenile idiopathic arthritis.

- Xeljanz XR is an extended-release tablet form of Xeljanz that is taken once a day.

Xeljanz works by **decreasing the activity of the immune system**. It does this by blocking the activity of JAK enzymes (JAK1, JAK2, JAK3, TYK2) inside the cell – these enzymes are responsible for sending inflammatory signals in the body which are associated with cytokine release. Xeljanz's mechanism of action of blocking these enzymes helps to decrease the immune reaction which causes rheumatoid arthritis, psoriatic arthritis, and ulcerative colitis.

Xeljanz was FDA-approved on November 6, 2012, and was the first JAK inhibitor to be approved for rheumatoid arthritis.

## Xeljanz uses

Xeljanz or Xeljanz XR may be used to treat the following conditions in adults who are unable to take or did not respond to one or more tumor necrosis factor (TNF) inhibitor medication(s):

- moderate to severe rheumatoid arthritis
- active psoriatic arthritis
- moderate to severe ulcerative colitis
- ankylosing spondylitis.

Xeljanz and Xeljanz oral solution are also approved to treat polyarticular juvenile idiopathic arthritis in patients 2 years of age and older who have had an inadequate response or intolerance to one or more TNF blockers.

Using Xeljanz along with other medications that suppress the immune system can increase the risk of serious side

effects. Tell your healthcare provider about all the medications you take.

## Xeljanz side effects

The **most common side effects of Xeljanz** are:

- skin rash, acne, shingles
- upper respiratory tract infection or cold symptoms such as stuffy nose, sneezing, sore throat
- increased blood pressure
- diarrhea
- abnormal blood tests
- elevated cholesterol levels
- fever
- [headache](#)
- nausea, or vomiting.

## Serious side effects and warnings

Xeljanz and Xeljanz XR carry a **Boxed Warning** for serious infections, death, cancer, cardiovascular events, and blood clots.

**Serious infections.** Xeljanz is a medicine that affects your immune system and can lower the ability of your immune system to fight infections. Some people can have serious infections while taking Xeljanz, including tuberculosis (TB), and infections caused by bacteria, fungi, or viruses that can spread throughout the body. Some people have died from these infections.

- Your healthcare provider should test you for TB before starting Xeljanz and during treatment.
- Your healthcare provider should monitor you closely for signs and symptoms of TB infection during treatment with Xeljanz.
- You should not start taking Xeljanz if you have any kind of infection unless your healthcare provider tells you it is okay. You may be at a higher risk of developing shingles (herpes zoster).
- People with ulcerative colitis taking the higher dose of Xeljanz (10 mg twice daily) or Xeljanz XR (22 mg one time each day) have a higher risk of serious infections and shingles.

After starting Xeljanz, call your healthcare provider right away if you have any symptoms of an infection. Xeljanz can make you more likely to get infections or make existing infections worse.

**Taking Xeljanz is associated with an increased risk of death** and major cardiovascular events (such as heart attack or stroke) in people 50 years of age and older who have at least 1 heart disease (cardiovascular) risk factor especially if they are a current or past smoker. Get emergency help right away if you have any symptoms of a heart attack or stroke while taking Xeljanz, including:

- discomfort in the center of your chest that lasts for more than a few minutes, or that goes away and comes back
- severe tightness, pain, pressure, or heaviness in your chest, throat, neck, or jaw

- pain or discomfort in your arms, back, neck, jaw, or stomach • shortness of breath with or without chest discomfort
- breaking out in a cold sweat
- nausea or vomiting
- feeling lightheaded
- weakness in one part or on one side of your body
- slurred speech.

**Cancer and immune system problems.** Xeljanz may increase your risk of certain cancers by changing the way your immune system works. People taking Xeljanz have a higher risk of certain cancers including lymphoma and lung cancer, especially if you are a current or past smoker. People with ulcerative colitis taking higher dosages of Xeljanz have a higher risk of skin cancers. Tell your healthcare provider if you have ever had any type of cancer.

Some people who have taken Xeljanz with certain other medicines to prevent kidney transplant rejection have had a problem with certain **white blood cells growing out of control** (Epstein Barr Virus-associated post-transplant lymphoproliferative disorder).

**Blood clots in the lungs, veins of the legs or arms, and arteries.** Blood clots in the lungs (pulmonary embolism, PE), veins of the legs (deep vein thrombosis, DVT), and arteries (arterial thrombosis) have happened more often in people who are 50 years of age and older and with at least 1 heart disease (cardiovascular) risk factor taking Xeljanz 5 mg twice daily or Xeljanz 10 mg twice daily. Blood clots in the lungs have also happened in people with ulcerative colitis. Some people have died from these blood clots. Stop taking Xeljanz and tell your healthcare provider right away if you develop signs and symptoms of a blood clot, such as sudden shortness of breath or difficulty breathing, chest pain, swelling of the leg or arm, leg pain or tenderness, or redness or discoloration in the leg or arm.

**Tears (perforation) in the stomach or intestines.** This happens most often in people who also take nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids, or methotrexate. Tell your healthcare provider right away if you have a fever, stomach-area pain that does not go away, and a change in your bowel habits.

**Allergic reactions.** Symptoms such as swelling of your lips, tongue, or throat, or hives (raised, red patches of skin that are often very itchy) that may mean you are having an allergic reaction have been seen in people taking Xeljanz. Some of these reactions were serious. If any of these symptoms occur while you are taking Xeljanz, stop taking it and call your healthcare provider right away.

**Hepatitis B or C activation** in people who carry the virus in their blood. If you are a carrier of the hepatitis B or C virus (viruses that affect the liver), the virus may become active while you use Xeljanz. Your healthcare provider may do blood tests before you start treatment with Xeljanz and while you are taking Xeljanz. Tell your healthcare provider if you have any of the following symptoms of a possible hepatitis B or C infection:

- feel very tired
- skin or eyes look yellow
- little or no appetite
- vomiting
- clay-colored bowel movements
- fevers
- chills

- stomach discomfort
- muscle aches
- dark urine
- skin rash.

**Changes in certain laboratory test results.** Your healthcare provider should do blood tests before you start taking Xeljanz and while you are taking it:

- changes in lymphocyte or neutrophil counts (these are both white blood cells that help the body fight off infections)
- low red blood cell counts. This may mean that you have anemia, which may make you feel weak and tired
- liver tests.

Your healthcare provider may stop your Xeljanz treatment for a period if needed because of changes in these blood test results.

You may also have changes in other laboratory tests, such as your **blood cholesterol levels**. Your healthcare provider should do blood tests to check your cholesterol levels 4 to 8 weeks after you start taking Xeljanz, and as needed after that. Normal cholesterol levels are important to good heart health.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

 [Xeljanz side effects](#) (more detail)

## Related/similar drugs

### Rinvoq

Rinvoq (upadacitinib) is used to treat rheumatoid arthritis, psoriatic arthritis, atopic ...

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### Dexamethasone

Dexamethasone is used to treat inflammatory conditions such as allergies, skin conditions ...

#### Reviews & ratings

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## Before taking

Do not take Xeljanz if:

- you have reacted to tofacitinib, Xeljanz, or any of the inactive ingredients contained in Xeljanz or Xeljanz XR tablets, or Xeljanz oral solution
- your lymphocytes, neutrophils, or hemoglobin levels are below the recommended level. Talk with your healthcare provider about this
- you have an active serious or localized infection or severe liver disease.

Before taking Xeljanz, tell your healthcare provider about all of your medical conditions, including if you:

- have an infection, including chronic infections such as tuberculosis, shingles, HIV, or hepatitis. Symptoms of an infection include fever, sweating, chills, muscle aches, cough, shortness of breath, blood in phlegm, weight loss, diarrhea or stomach pain, burning when you urinate or urinating more often than normal, feeling very tired, or warm,

red, or painful skin or sores on your body.

- have diabetes, chronic lung disease, HIV, or a weak immune system. People with these conditions have a higher chance of infections
- live or have lived, or have traveled to certain parts of the country (such as the Ohio and Mississippi River valleys and the Southwest) where there is an increased chance for getting certain kinds of fungal infections (histoplasmosis, coccidioidomycosis, or blastomycosis). These infections may happen or become more severe if you take Xeljanz. Ask your healthcare provider if you do not know if you have lived in an area where these infections are common
- have had any type of cancer
- have had a heart attack, other heart problems, or stroke
- have had blood clots in the veins of your legs, arms, or lungs, or clots in the arteries in the past
- have liver or kidney problems
- have any stomach area (abdominal) pain or been diagnosed with diverticulitis or ulcers in your stomach or intestines
- [high cholesterol](#)
- have recently received or are scheduled to receive a vaccine. People who take Xeljanz should not receive live vaccines. People taking Xeljanz can receive non-live vaccines
- are a current or past smoker
- plan to become pregnant or are pregnant
- plan to breastfeed or are breastfeeding.

Using Xeljanz may increase your risk of developing certain cancers, such as [lymphoma](#) or [lung cancer](#). Ask your doctor about this risk.

Do not give this medicine to a child without medical advice. Xeljanz XR (extended-release) tablets are not approved for use by anyone younger than 18 years.

## Pregnancy and fertility

It is not known if Xeljanz will harm an unborn baby. Having rheumatoid arthritis or ulcerative colitis during pregnancy may increase the risk of premature birth or low birth weight. The benefit of treating these conditions with Xeljanz may outweigh any risks to the baby.

Pfizer has a **registry for pregnant women who take Xeljanz**. The purpose of this registry is to check the health of the pregnant mother and her baby. If you are pregnant or become pregnant while taking Xeljanz, talk to your healthcare provider about how you can join this pregnancy registry or you may contact the registry at 1-877-311-8972 to enroll.

If you are a woman, Xeljanz may affect your fertility and your ability to have children during treatment and in the future.

## Breastfeeding

Do not breastfeed while you are using this medicine, and for at least 18 hours after your last dose (36 hours if you take extended-release tablets). If you use a breast pump during this time, do not feed the milk to your baby.

 [Xeljanz pregnancy and breastfeeding warnings](#) (more detail)

# How do I take Xeljanz, Xeljanz XR, or Xeljanz oral solution?

Take Xeljanz, Xeljanz XR, and Xeljanz oral solution exactly as your healthcare provider tells you to take it. Follow all directions on your prescription label and read all medication guides or instruction sheets. Your doctor may occasionally change your dose.

- **Xeljanz** is taken 2 times a day, with or without food.
- **Xeljanz oral solution** is taken 2 times a day, with or without food.
  - Measure liquid medicine with the supplied measuring device (not a kitchen spoon).
- **Xeljanz XR** is taken 1 time a day, with or without food.
  - Swallow Xeljanz XR whole and do not crush, chew, or break it.
  - When you take Xeljanz XR, you may see something in your stool that looks like a tablet. The active medication has already been absorbed by the time the inert tablet shell has passed.
  - Xeljanz XR (extended-release tablets) are not interchangeable or substitutable with Xeljanz Oral Solution.

For the treatment of psoriatic arthritis, take Xeljanz/Xeljanz XR in combination with methotrexate, sulfasalazine, or leflunomide as instructed by your healthcare provider.

Do not use in people with severe liver disease.

Regular laboratory monitoring is recommended due to potential changes in lymphocytes, neutrophils, hemoglobin, liver enzymes, and lipids.

 [Xeljanz patient tips](#) (more detail)

## Xeljanz dosing information

### Xeljanz dosing for adults with rheumatoid arthritis, psoriatic arthritis, or ankylosing spondylitis

- Xeljanz 5 mg twice a day

OR

- Xeljanz XR 11 mg once a day.

#### Notes:

Moderate to severe renal impairment or moderate hepatic impairment. Reduce the dosage to Xeljanz 5mg once daily.

Psoriatic arthritis: use in combination with nonbiologic DMARDs.

### Xeljanz dosing for adults with ulcerative colitis

- Induction (at least 8 weeks): Xeljanz 10 mg orally twice a day OR Xeljanz XR 22 mg once daily
- Maintenance: Xeljanz 5 mg orally twice a day or Xeljanz XR 11 mg once a day.

#### Notes:



If needed, induction dosages may be continued for up to 16 weeks; if adequate therapeutic response is not achieved after 16 weeks, the induction dosage should be discontinued.

For patients with loss of response during maintenance therapy, consider Xeljanz 10 mg orally twice a day or Xeljanz XR 22 mg orally once a day for a short duration. Use the lowest effective dose needed to maintain a response.

## Xeljanz dosing for polyarticular course juvenile idiopathic arthritis

Doses are based on weight in children and teenagers who weigh less than 88 pounds (40 kg). Your child's dose may change if the child gains or loses weight.

- Weight 22 lb (10 kg) to < 44 lb (20 kg): Xeljanz oral solution 3.2 mg orally twice a day
- Weight 44 lb (20 kg) to < 88 lb (40 kg): Xeljanz oral solution 4 mg orally twice a day
- Weight at least 88 lb (40 kg): Xeljanz oral solution 5 mg orally twice a day OR Xeljanz 5 mg orally twice a day.

### Notes:

Children must be aged 2 years or older.

 [Detailed Xeljanz dosage information](#)

## What happens if I miss a dose?

Take the medicine as soon as you can, but skip the missed dose if it is almost time for your next dose. Do not take two doses at one time.

## What happens if I overdose?

If you take too much Xeljanz, Xeljanz XR, or Xeljanz Oral Solution, call your healthcare provider, the Poison Help line at 1-800-222-1222, or go to the nearest hospital emergency room right away.

## What should I avoid while taking Xeljanz?

Avoid receiving a "live" vaccine. Live vaccines include [measles](#), mumps, [rubella](#) (MMR), rotavirus, typhoid, yellow fever, varicella (chickenpox), and zoster (shingles).

## What other drugs will affect Xeljanz?

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Xeljanz and other medicines may affect each other causing side effects. Especially tell your healthcare provider if you take:

- **any other medicines to treat your rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, ulcerative colitis or polyarticular juvenile arthritis** such as tocilizumab (Actemra), etanercept (Enbrel), adalimumab (Humira), infliximab (Remicade), rituximab (Rituxan), abatacept (Orencia), anakinra (Kineret), certolizumab (Cimzia), golimumab (Simponi), ustekinumab (Stelara), secukinumab (Cosentyx), vedolizumab (Entyvio), ixekizumab (Taltz), azathioprine, cyclosporine, or other immunosuppressive drugs while you are taking Xeljanz. Taking Xeljanz with these medicines may increase your risk of infection.

- moderate CYP3A4 inhibitors/strong CYP2C19 inhibitors (eg, fluconazole)
- strong CYP3A4 inducers (eg, rifampin)
- strong CP3A4 inhibitors (such as ketoconazole)
- tacrolimus
- medicines that affect the way certain liver enzymes work. Ask your healthcare provider if you are not sure if your medicine is one of these.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine. This list is not complete and many other drugs may interact with tofacitinib. This includes prescription and over-the-counter medicines, [vitamins](#), and [herbal products](#). Not all possible drug interactions are listed here.

 [Xeljanz drug interactions](#) (more detail)

## Does Xeljanz interact with my other drugs?

Enter medications to view a detailed interaction report using our [Drug Interaction Checker](#).

Xeljanz

+

Enter a drug name

Add

## Xeljanz ingredients

**Active ingredient:** tofacitinib citrate

**Inactive ingredients:**

- **Xeljanz 5 mg:** croscarmellose sodium, HPMC 2910/Hypromellose 6cP, lactose monohydrate, macrogol/PEG3350, magnesium stearate, microcrystalline cellulose, titanium dioxide, and triacetin.
- **Xeljanz 10 mg:** croscarmellose sodium, FD& C Blue #1/Brilliant Blue FCF Aluminum Lake, FD& C Blue #2/Indigo Carmine Aluminum Lake, HPMC 2910/Hypromellose 6cP, lactose monohydrate, macrogol/PEG3350, magnesium stearate, microcrystalline cellulose, titanium dioxide, and triacetin.
- **Xeljanz XR 11 mg:** cellulose acetate, copovidone, hydroxyethyl cellulose, hydroxypropyl cellulose, HPMC 2910/Hypromellose, magnesium stearate, red iron oxide, sorbitol, titanium dioxide, and triacetin. The printing ink contains ammonium hydroxide, ferrosoferric oxide/black iron, propylene glycol, and shellac glaze.
- **Xeljanz XR 22 mg:** cellulose acetate, copovidone, FD& C Blue #2 Aluminum Lake, hydroxyethyl cellulose, hydroxypropyl cellulose, HPMC 2910/Hypromellose, magnesium stearate, red iron oxide, sorbitol, titanium dioxide, triacetin, and yellow iron oxide. The printing ink contains ammonium hydroxide, ferrosoferric oxide/black iron oxide, propylene glycol, and shellac glaze.
- **Xeljanz oral solution 1mg/mL:** grape flavor (natural), hydrochloric acid, lactic acid, purified water, sodium benzoate, sucralose, and xylitol.

## Availability

Xeljanz tablets: 5 mg, 10 mg

Xeljanz XR Tablets: 11 mg, 22 mg tofacitinib

Xeljanz Oral Solution: 1 mg/mL tofacitinib

## Storage

Store **Xeljanz** and **Xeljanz XR** at room temperature between 68°F to 77°F (20°C to 25°C).

Store **Xeljanz Oral Solution** at room temperature between 68°F to 77°F (20°C to 25°C). Use within 60 days of opening the bottle. Throw away (discard) the remaining solution after 60 days. Write the date when you first start to use the solution on the carton.

Keep it in the original bottle and carton to protect it from light.

Keep out of reach of children.

## Who makes Xeljanz, Xeljanz XR, and Xeljanz oral solution?

Pfizer Inc. manufactures Xeljanz, Xeljanz XR, and Xeljanz oral solution.

## Popular FAQ

What are JAK inhibitors and how do they work?



Which JAK inhibitors are approved in the U.S?



What happens when you stop taking Xeljanz?



How long does Xeljanz take to work?



Can I drink alcohol while taking Xeljanz?



Does Xeljanz cause hair loss?



What is Xeljanz used for and is it a biologic?



Is Xeljanz an immunosuppressant?



## More FAQ

- [What are the new drugs for rheumatoid arthritis \(RA\)?](#)

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## References

1. [Xeljanz Package Insert](#)
2. [Padda IS, Bhatt R, Parmar M. Tofacitinib. \[Updated 2022 Jan 6\]. In: StatPearls \[Internet\]. Treasure Island \(FL\): StatPearls Publishing; 2022 Jan-.](#)

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## Professional resources

- [Xeljanz prescribing information](#)
- [Tofacitinib \(AHFS Monograph\)](#)

## Related treatment guides

- [Ankylosing Spondylitis](#)
- [Psoriatic Arthritis](#)
- [Rheumatoid Arthritis](#)
- [Polyarticular Juvenile Idiopathic Arthritis](#)
- [Ulcerative Colitis](#)

## Further information

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

## DRUG STATUS

### Availability

**Rx** Prescription only

### Pregnancy & Lactation

 Risk data available

### CSA Schedule\*

**N/A** Not a controlled drug

### Approval History

**10+ years** FDA approved 2012



## User Reviews & Ratings

5.7 / 10

[145 Reviews](#)

## Images

[Xeljanz 5 mg \(Pfizer JKI 5\)](#)



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