

# HEALTH NEWS

## Treating Rheumatoid Arthritis

### Pfizer Knows JAK Science

Pfizer is the leader in JAK science with more than 20 years dedicated to the discovery and development of XELJANZ for the treatment of moderate to severe rheumatoid arthritis (RA).

**XELJANZ®** (tofacitinib citrate) 5 mg tablets and **XELJANZ® XR** (tofacitinib citrate) extended-release 11 mg tablets

#### The Development of XELJANZ, the First and Only Approved Oral JAK Inhibitor for Moderate to Severe RA

1993

The discovery and development process involved **screening hundreds of thousands** of compounds leading to the identification of tofacitinib

Tofacitinib advanced to clinical trials **in moderate to severe RA**

**XELJANZ 5 mg twice-daily launches in the US**

XELJANZ US label updated to include data on the **reduction of the progression of structural joint damage**

One of the **fastest growing RA therapies** in the US<sup>1</sup>

XELJANZ® XR approved by FDA as the **first and only once-daily oral JAK inhibitor available** for patients with moderate to severe RA

#### XELJANZ 5 mg twice-daily



The **largest body of clinical evidence** of any JAK inhibitor in moderate to severe RA. XELJANZ has been studied in 6,194 adults representing over 19,400 years of patient experience spanning over seven years as of March 2015.



XELJANZ XR 11 mg administered once daily is pharmacokinetically equivalent to XELJANZ (tofacitinib citrate) 5 mg administered twice daily.

Pfizer is committed to enhancing the science and understanding of XELJANZ/XELJANZ XR through a **robust clinical development program**

#### WHAT IS XELJANZ/XELJANZ XR?

XELJANZ/XELJANZ XR is a prescription medicine called a Janus kinase (JAK) inhibitor. XELJANZ/XELJANZ XR is used to treat adults with moderately to severely active rheumatoid arthritis in which methotrexate did not work well.

It is not known if XELJANZ/XELJANZ XR is safe and effective in people with hepatitis B or C.

XELJANZ/XELJANZ XR is not for people with severe liver problems.

It is not known if XELJANZ/XELJANZ XR is safe and effective in children.

#### IMPORTANT SAFETY INFORMATION

What is the most important information I should know about XELJANZ/XELJANZ XR?

XELJANZ/XELJANZ XR may cause serious side effects, including:

**Serious infections.** XELJANZ/XELJANZ XR can lower the ability of your immune system to fight infections. Some people can have serious infections while taking XELJANZ/XELJANZ XR, 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/XELJANZ XR, and monitor you closely for signs and symptoms of TB infection during treatment. You should not start taking XELJANZ/XELJANZ XR 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.

Before starting XELJANZ/XELJANZ XR, tell your healthcare provider if you:

- think you have an infection or have symptoms of an infection, such as fever, sweating, or chills; cough; blood in phlegm; warm, red, or painful skin or sores on your body; burning when you urinate or urinating more often than normal; muscle aches; shortness of breath; weight loss; diarrhea or stomach pain; or feeling very tired
- are being treated for an infection
- get a lot of infections or have infections that keep coming back
- have diabetes, HIV, or a weak immune system. People with these conditions have a higher chance for infections
- have TB, or have been in close contact with someone with TB
- live or have lived in, 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 use XELJANZ/XELJANZ XR. Ask your healthcare provider if you do not know if you have lived in an area where these infections are common
- have or have had hepatitis B or C

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

**Cancer and immune system problems.** XELJANZ/XELJANZ XR may increase your risk of certain cancers by changing the way your immune system works. Lymphoma and other cancers, including skin cancers, have happened in patients taking XELJANZ/XELJANZ XR. Tell your healthcare provider if you have ever had any type of cancer.

Some people who have taken XELJANZ/XELJANZ XR 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).

**Tears (perforation) in the stomach or intestines.** Some people taking XELJANZ/XELJANZ XR can get tears in their stomach or intestine. 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 fever and stomach-area pain that does not go away and a change in your bowel habits.

**Changes in certain lab test results.** Your healthcare provider should do blood tests before you start receiving XELJANZ/XELJANZ XR, and while you take XELJANZ/XELJANZ XR, to check for the following side effects:

- **changes in lymphocyte counts.** Lymphocytes are white blood cells that help the body fight off infections.
- **low neutrophil counts.** Neutrophils are white blood cells that help the body fight off infections.
- **low red blood cell count.** This may mean that you have anemia, which may make you feel weak and tired.

Your healthcare provider should routinely check certain liver tests.

You should not receive XELJANZ/XELJANZ XR if your lymphocyte count, neutrophil count, or red blood cell count is too low or your liver tests are too high. Your healthcare provider may stop your XELJANZ/XELJANZ XR treatment for a period of time if needed because of changes in these blood test results.

Your healthcare provider should do blood tests to check your cholesterol levels 4-8 weeks after you start XELJANZ/XELJANZ XR, and as needed after that.

What should I tell my healthcare provider before taking XELJANZ/XELJANZ XR?

XELJANZ/XELJANZ XR may not be right for you. Before taking XELJANZ/XELJANZ XR, tell your healthcare provider if you:

- have an infection
  - have liver problems
  - have kidney problems
  - have any stomach area (abdominal) pain or been diagnosed with diverticulitis (inflammation in parts of the large intestine) or ulcers in your stomach or intestines or narrowing within your digestive tract
  - have had a reaction to tofacitinib or any of the ingredients in XELJANZ/XELJANZ XR
  - have recently received or are scheduled to receive a vaccine. People taking XELJANZ/XELJANZ XR should not receive live vaccines but can receive non-live vaccines
  - have any other medical conditions
  - plan to become pregnant or are pregnant. It is not known if XELJANZ will harm an unborn baby
- Pregnancy Registry:** 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
- plan to breastfeed or are breastfeeding

Tell your healthcare provider about all of the medicines you take, especially any other medicines to treat your rheumatoid arthritis. You should not take tocilizumab (Actemra®), etanercept (Enbrel®), adalimumab (Humira®), infliximab (Remicade®), rituximab (Rituxan®), abatacept (Orencia®), anakinra (Kineret®), certolizumab pegol (Cimzia®), golimumab (Simponi®), azathioprine, cyclosporine, or other immunosuppressive drugs while you are taking XELJANZ/XELJANZ XR. Taking XELJANZ with these medicines may increase your risk of infection.

- Tell your healthcare provider if you are taking 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.

#### Taking XELJANZ XR

When you take XELJANZ XR, you may see something in your stool that looks like a tablet. This is the empty shell from the tablet after the medicine has been absorbed by your body.

#### What are other possible side effects of XELJANZ/XELJANZ XR?

XELJANZ/XELJANZ XR may cause serious side effects, including hepatitis B or C activation infection 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/XELJANZ XR. Tell your healthcare provider if you have the following symptoms of a possible hepatitis B or C infection: feel very tired, little or no appetite, clay-colored bowel movements, chills, muscle aches, skin rash, skin or eyes look yellow, vomiting, fevers, stomach discomfort, or dark urine.

Common side effects of XELJANZ/XELJANZ XR include upper respiratory tract infections (common cold, sinus infections), headache, diarrhea, and nasal congestion, sore throat, and runny nose (nasopharyngitis).

Please see full Prescribing Information, including BOXED WARNING and Medication Guide, available at [www.xeljanzpi.com](http://www.xeljanzpi.com).



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(tofacitinib citrate)  
5 mg tablets

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(tofacitinib citrate)  
extended-release • 11 mg tablets



**(NAPSA)—The FDA has approved a pill that can help bring relief to people with rheumatoid arthritis (RA).**