

MEDICATION GUIDE

Tofacitinib (toe'' fa sye' ti nib) extended-release tablets, for oral use

What is the most important information I should know about tofacitinib extended-release tablets?

Tofacitinib extended-release tablets may cause serious side effects including:

1. Serious infections. Tofacitinib is a medicine that affects your immune system. Tofacitinib can lower the ability of your immune system to fight infections. Some people can have serious infections while taking tofacitinib, 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 tofacitinib extended-release tablets and during treatment.
- Your healthcare provider should monitor you closely for signs and symptoms of TB infection during treatment with tofacitinib extended-release tablets.

You should not start taking tofacitinib extended-release tablets 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 tofacitinib tablets (10 mg twice daily) or tofacitinib extended-release tablets (22 mg one time each day) have a higher risk of serious infections and shingles. Before starting tofacitinib extended-release tablets, 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
 - feeling very tired
- are being treated for an infection.
- get a lot of infections or have infections that keep coming back.
- have diabetes, chronic lung disease, 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, 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 tofacitinib. 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 tofacitinib extended-release tablets, call your healthcare provider right away if you have any symptoms of an infection. Tofacitinib extended-release tablets can make you more likely to get infections or make worse any infection that you have.

2. Increased risk of death in people 50 years of age and older who have at least 1 heart disease (cardiovascular) risk factor and are taking tofacitinib 5 mg or 10 mg twice daily.

3. Cancer and immune system problems. Tofacitinib may increase your risk of certain cancers by changing the way your immune system works.

- Lymphoma and other cancers including skin cancers can happen in people taking tofacitinib. People taking tofacitinib 5 mg twice daily or tofacitinib 10 mg twice daily 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 the higher dose of tofacitinib tablets (10 mg twice daily) or tofacitinib extended-release tablets (22 mg one time each day) have a higher risk of skin cancers. Tell your healthcare provider if you have ever had any type of cancer.

4. Increased risk of major cardiovascular events such as heart attack, stroke or death in people 50 years of age and older who have at least 1 heart disease (cardiovascular) risk factor and are taking tofacitinib 5 mg or 10 mg twice daily, especially if you are a current or past smoker.

Get emergency help right away if you have any symptoms of a heart attack or stroke while taking Tofacitinib extended-release tablets, 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

5. 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 tofacitinib 5 mg or 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 tofacitinib extended-release tablets 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.

6. Tears (perforation) in the stomach or intestines.

- Tell your healthcare provider if you have had diverticulitis (inflammation in parts of the large intestine) or ulcers in your stomach or intestines. Some people taking tofacitinib can get tears in their 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 fever and stomach-area pain that does not go away, and a change in your bowel habits.

7. 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 tofacitinib tablets/tofacitinib extended-release tablets. Some of these reactions were serious. If any of these symptoms occur while you are taking tofacitinib extended-release tablets, stop tofacitinib extended-release tablets and call your healthcare provider right away.

8. Low blood sugar (hypoglycemia) in people with diabetes. If you have diabetes, your healthcare provider may tell you to check your blood sugar (glucose) more often during treatment with tofacitinib extended-release tablets. Call your healthcare provider if you have any problems with low blood sugar.

9. Changes in certain laboratory test results. Your healthcare provider should do blood tests before you start taking tofacitinib extended-release tablets and while you take tofacitinib extended-release tablets 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 take tofacitinib extended-release tablets 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 tofacitinib extended-release tablets treatment for a period of time 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 tofacitinib extended-release tablets, and as needed after that. Normal cholesterol levels are important to good heart health.

See “**What are the possible side effects of tofacitinib extended-release tablets?**” for more information about side effects.

What is tofacitinib extended-release tablets?

- Tofacitinib is a prescription medicine called a Janus kinase (JAK) inhibitor. Tofacitinib extended-release tablets is used to treat adults with moderately to severely active rheumatoid arthritis when 1 or more medicines called tumor necrosis factor (TNF) blockers have been used and did not work well or cannot be tolerated.
- Tofacitinib extended-release tablets is used to treat adults with active psoriatic arthritis when 1 or more TNF blocker medicines have been used, and did not work well or cannot be tolerated.
- Tofacitinib extended-release tablets is used to treat adults with active ankylosing spondylitis when 1 or more TNF blocker medicines have been used and did not work well or cannot be tolerated.
- Tofacitinib extended-release tablets is used to treat adults with moderately to severely active ulcerative colitis when 1 or more TNF blocker medicines have been used, and did not work well or cannot be tolerated.

It is not known if tofacitinib extended-release tablets is safe and effective in people with Hepatitis B or C.

Tofacitinib extended-release tablets is not recommended for people with severe liver problems.

It is not known if tofacitinib extended-release tablets is safe and effective in children.

What should I tell my healthcare provider before taking tofacitinib extended-release tablets?

Before taking tofacitinib extended-release tablets, tell your healthcare provider about all of your medical conditions, including if you:

- have an infection. See **“What is the most important information I should know about tofacitinib extended-release tablets?”**
- are a current or past smoker.
- 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 problems.
- have kidney problems.
- have any stomach-area (abdominal) pain or been diagnosed with diverticulitis or ulcers in your stomach or intestines.
- have diabetes.
- have had a reaction to tofacitinib or any of the ingredients in tofacitinib extended-release tablets.
- have recently received or are scheduled to receive a vaccine. People who take tofacitinib extended-release tablets should not receive live vaccines. People taking tofacitinib extended-release tablets can receive non-live vaccines.
- plan to become pregnant or are pregnant. Tofacitinib extended-release tablets may affect the ability of females to get pregnant. It is not known if this will change after stopping tofacitinib extended-release tablets. It is not known if tofacitinib extended-release tablets will harm an unborn baby.
- plan to breastfeed or are breastfeeding. You and your healthcare provider should decide if you will take tofacitinib extended-release tablets or breastfeed. You should not do both. After you stop your treatment with tofacitinib do not start breastfeeding again until:
 - 36 hours after your last dose of tofacitinib extended-release tablets

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Tofacitinib extended-release tablets 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 or ulcerative colitis. You should not take 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 tofacitinib extended-release tablets. Taking tofacitinib extended-release tablets with these medicines may increase your risk of infection.

- 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.

How should I take tofacitinib extended-release tablets?

Take tofacitinib extended-release tablets exactly as your healthcare provider tells you to take it.

- Take tofacitinib extended-release tablets 1 time a day with or without food.
- Swallow tofacitinib extended-release tablets whole and intact. Do not crush, split, or chew.
- If you take too much tofacitinib extended-release tablets, call your healthcare provider or go to the nearest hospital emergency room right away.
- For the treatment of psoriatic arthritis, take tofacitinib extended-release tablets in combination with methotrexate, sulfasalazine or leflunomide as instructed by your healthcare provider.
- Tofacitinib extended-release tablets should not be used instead of tofacitinib oral solution.

What are the possible side effects of tofacitinib extended-release tablets?

Tofacitinib extended-release tablets may cause serious side effects, including:

- See “**What is the most important information I should know about tofacitinib extended-release tablets?**”
- **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 tofacitinib extended-release tablets. Your healthcare provider may do blood tests before you start treatment with tofacitinib extended-release tablets and while you are taking tofacitinib extended-release tablets. Tell your healthcare provider if you have any of 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
 - dark urine

Common side effects of tofacitinib tablets/tofacitinib extended-release tablets in people with rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis include:

- upper respiratory tract infections (common cold, sinus infections)
- headache
- diarrhea
- nasal congestion, sore throat, and runny nose (nasopharyngitis)
- high blood pressure (hypertension)
- acne

Common side effects of tofacitinib tablets/tofacitinib extended-release tablets in people with ulcerative colitis include:

- nasal congestion, sore throat, and runny nose (nasopharyngitis)
- increased cholesterol levels
- headache
- upper respiratory tract infections (common cold, sinus infections)
- increased muscle enzyme levels
- rash
- acne
- diarrhea
- shingles (herpes zoster)

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of tofacitinib. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

You may also report side effects to Edenbridge Pharmaceuticals, LLC DBA Dexcel Pharma USA at 1-877-381-3336.

How should I store tofacitinib extended-release tablets?

- Store tofacitinib extended-release tablets at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F).

Keep tofacitinib extended-release tablets and all medicines out of the reach of children.

General information about the safe and effective use of tofacitinib extended-release tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use tofacitinib extended-release tablets for a condition for which it was not prescribed. Do not give tofacitinib extended-release tablets to other people, even if they have the same symptoms you have. It may harm them.

This Medication Guide summarizes the most important information about tofacitinib extended-release tablets. If you would like more information, talk to your healthcare provider. You can ask your pharmacist or healthcare provider for information about tofacitinib extended-release tablets that is written for health professionals.

What are the ingredients in tofacitinib extended-release tablets 11 mg?

Active ingredient: tofacitinib citrate

Inactive ingredients: colloidal silicon dioxide, hypromellose 2208 K100LV, mannitol DC200, hydroxypropyl cellulose (Klucel EXF), magnesium stearate and pink film coating. Coloring film coat contains: hypromellose 2910, titanium dioxide, triacetin and iron oxide red.

Manufactured by:

Dexcel Pharma Technologies Ltd.
Yokneam Illit 2069200, Israel

Manufactured for:

Edenbridge Pharmaceuticals, LLC
DBA Dexcel Pharma USA, Parsippany, NJ 07054
877-381-3336

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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