

Xeltin Tablets
Tofacitinib Tablets 5mg

Patient Information Leaflet

Read all of this leaflet carefully before you start using 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet?

1. What Xeltin Tablet is and what it is used for
2. What you need to know before you use Xeltin Tablet
3. How to use Xeltin Tablet
4. Possible side effects
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1. What Xeltin Tablet is and what it is used for

XELTIN is a medicine that contains the active substance tofacitinib.

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

- Rheumatoid arthritis
- Psoriatic arthritis
- Ulcerative colitis

Rheumatoid arthritis

XELTIN 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.

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

XELTIN 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

XELTIN is used to treat 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 XELTIN to reduce the sign and symptoms of active psoriatic arthritis and improve the ability to perform daily activities.

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

Ulcerative colitis

Ulcerative colitis is an inflammatory disease of the large bowel.

XELTIN is used to reduce the signs and symptoms of ulcerative colitis when you did not respond well enough or were intolerant to previous ulcerative colitis treatment.

2. What you need to know before you use Xeltin Tablet

Do not use Xeltin Tablet

- If you are allergic to Tofacitinib or any of the other ingredients of this medicine.
- 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 our doctor.

Warnings and precautions

- Talk to your doctor or pharmacist before taking XELTIN:
- 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. XELTIN 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 XELTIN 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
- XELTIN. Your doctor may do blood tests for hepatitis before you start treatment with XELTIN and while you are taking XELTIN.
- If you have ever had any type of cancer. XELTIN may increase your risk of certain cancers. Lymphoma and other cancers (such as lung, breast, and melanoma, prostate and pancreatic) have been reported in patients treated with XELTIN. If you develop cancer while taking XELTIN your doctor will review whether to stop XELTIN treatment.
- If you are at high risk of developing skin cancer, your doctor may recommend that you have regular skin examinations while taking XELTIN.
- If you have had diverticulitis (a type of inflammation of the large intestine) or ulcers in stomach or intestines.
- 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 XELTIN.
- Before you start XELTIN, 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, or high cholesterol.
- Additional monitoring tests
- Your doctor should perform blood tests before you start taking

- XELTIN, 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 XELTIN if your white blood cell (neutrophil or lymphocyte) count or red blood cell count is too low. If needed, your doctor may interrupt your XELTIN 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 XELTIN. 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.

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.

Excipient effects:

The tablet contain lactose. Patient with rare hereditary problems of galactose intolerance, the Lapp Lactase deficiency or glucose – galactose malabsorption should not take this medicine.

Children and adolescents

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

Other medicines and XELTIN

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

Tofacitinib may be used in combination with methotrexate or sometimes alone when used to treat rheumatoid arthritis. In general, fewer side effects were seen when Tofacitinib was used alone in rheumatoid arthritis.

Some medicines should not be taken with Tofacitinib. If taken with Tofacitinib, they could alter the level of Tofacitinib in your body, and the dose of Tofacitinib 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 clarithromycin and rifampicin, used to treat bacterial infections.
- Fluconazole, ketoconazole, clotrimazole, itraconazole, and voriconazole, used to treat fungal infections.

Tofacitinib 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 immunosuppressant including azathioprine, mercaptopurine, cyclosporine, and tacrolimus. Taking Tofacitinib 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).

Pregnancy and breast-feeding

If you are a woman of childbearing age, you should use effective birth control during treatment with XELTIN 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. XELTIN must not be used during pregnancy.

Tell your doctor right away if you become pregnant while taking XELTIN.

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

Driving and using machines

XELTIN has no or limited effect on your ability to drive or use machines.

XELTIN 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.

3. How to use Xeltin Tablet

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

Always take this medicine exactly as your doctor has told you.

Check with your doctor or pharmacist if you are not sure.

Rheumatoid arthritis

The recommended dose is 5 mg twice a day.

Psoriatic arthritis

The recommended dose is 5 mg twice a day.

Ulcerative colitis

- The recommended dose is 10 mg twice a day for 8 weeks, followed by 5 mg twice a day.
- Your doctor may decide to extend the initial 10 mg twice a day treatment by an additional 8 weeks (16 weeks in total), followed by 5 mg twice a day.
- Your doctor may decide to stop XELTIN if XELTIN does not work for you within 16 weeks.
- For patients, who have previously taken biologic medicines to treat ulcerative colitis (such as those that block the activity of tumour necrosis factor in the body) and these medicines did not work, the doctor may decide to continue giving 10 mg twice a day. Your doctor will tell you if this applies to you.
- If maintaining XELTIN 5 mg twice a day did not work for you, your doctor may decide to increase the dose to 10 mg twice a day.

If your treatment is interrupted, your doctor may decide to restart your treatment.

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

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.

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

If you take more XELTIN than you should

If you take more tablets than you should, immediately tell your doctor or pharmacist.

If you forget to take XELTIN

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 XELTIN

You should not stop taking XELTIN 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.

Signs of serious infections (common) include

- Fever and chills
- Cough
- Skin blisters
- Stomach ache
- Persistent headaches

Signs of allergic reactions (rare) include

- Chest tightness
- Wheezing
- Severe dizziness or light-headedness
- Swelling of the lips, tongue or throat
- Hives (itching or skin rash)

Signs of stomach problems (uncommon: ulcers or holes in your stomach or intestines) 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).

Other side effects which have been observed with Tofacitinib 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, joint sprain, 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):

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, weight gain, dehydration, muscle strain, pain in the muscles and joints, tendonitis, joint swelling, 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), 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.

5. How to store Xeltin Tablet

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.

Store below 30°C. 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 Xeltin Tablet contains:

Xeltin (Tofacitinib Tablets 5mg)

Each film coated tablet contains:

Tofacitinib Citrate equivalent to	
Tofacitinib	5mg
Colour: Titanium Dioxide	
Excipients	q.s.

List of Excipients:

Microcrystalline Cellulose, Lactose Monohydrate, Lactose Monohydrate, Croscarmellose Sodium, Magnesium Stearate, Opadry 03B28796 White (Which contains Hypromellose, Titanium dioxide and Polyethylene Glycol/Macrogol) and Purified Water.

What Xeltin Tablet looks like and contents of the pack

Film-coated tablets.

White to off-white colored, round, biconvex film-coated tablets debossed with "T V" on one side and plain on other side.

The tablets are provided in Alu-PVC/PVdC blisters.

10 tablets are packed in Alu-PVC/PVdC blister, 3 such blisters are packed in a carton along with PIL.

Manufacturing Authorization Holder	Manufacturer
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For any information about this medicinal product, please contact Manufacturing Authorization Holder.

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