Read all of this leaflet carefully before you starts 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.
- 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.

WHAT IS IN THIS LEAFLET

1. WHAT JITRIT IS AND WHAT IT IS USED FOR

Jitrit is a medicine that contains the active substance tofacitinib.

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

- Rheumatoid arthritis
- Psoriatic arthritis
- Ulcerative colitis
- ankylosing spondylitis
- polyarticular juvenile idiopathic arthritis and juvenile psoriatic arthritis

Rheumatoid arthritis

Tofacitinib 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.

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

Tofacitinib 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: Tofacitinib 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 Tofacitinib to reduce the sign and symptoms of active psoriatic arthritis and improve the ability to perform daily activities.

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

Ankylosing spondylitis

Tofacitinib is used to treat a condition called ankylosing spondylitis. This condition is an inflammatory disease of the spine.

Tofacitinib can be used alone or together with other medicines to treat your ankylosing spondylitis.

Tofacitinib has been shown to reduce back pain and improve the ability to perform daily activities.

Ulcerative colitis: Ulcerative colitis is an inflammatory disease of the large bowel. Tofacitinib 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.

Polyarticular juvenile idiopathic arthritis and juvenile psoriatic arthritis

Tofacitinib is used for the treatment of active polyarticular juvenile idiopathic arthritis a long-term disease that mainly causes pain and swelling of your joints, in patients 2 years of age and older.

Tofacitinib is also used for the treatment of juvenile psoriatic arthritis, a condition that is an inflammatory disease of the joints often accompanied by psoriasis, in patients 2 years of age and older.

Tofacitinib can be used together with methotrexate when previous treatment for polyarticular juvenile idiopathic arthritis or juvenile psoriatic arthritis was not sufficient or was not well tolerated.

Tofacitinib can also be taken on its own in those cases where methotrexate treatment is not tolerated or treatment with methotrexate is not advised.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE JITRIT

Do not take Tofacitinib

- If you are allergic to tofacitinib or any of the other ingredients of this medicine (listed in section 6)
- 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 your doctor.

Warnings and precautions

Talk to your doctor or pharmacist before taking Tofacitinib:

- 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. Tofacitinib 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 Tofacitinib 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 Tofacitinib. Your doctor may do blood tests for hepatitis before you start treatment with Tofacitinib and while you are taking Tofacitinib

- 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. Tofacitinib 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 Tofacitinib. If you develop cancer while taking Tofacitinib your doctor will review whether to stop Tofacitinib treatment.

- If you are at high risk of developing skin cancer, your doctor may recommend that you have regular skin examinations while taking Tofacitinib.

- If you have had diverticulitis (a type of inflammation of the large intestine) or ulcers in stomach or intestines (see section 4)

- 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 Tofacitinib. Before you start Tofacitinib, 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, and also if you are a current or past smoker

There have been reports of patients treated with Tofacitinib 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 tofacitinib 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, your doctor may decide that Tofacitinib 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 Tofacitinib, as these may be signs of a clot in the lungs or veins.

There have been reports of patients treated with Tofacitinib who have had a heart problem, including heart attack. Your doctor will evaluate your risk to develop a heart problem and determine if Tofacitinib 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.

Additional monitoring tests

Your doctor should perform blood tests before you start taking tofacitinib, 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 Tofacitinib if your white blood cell (neutrophil or lymphocyte) count or red blood cell count is too low. If needed, your doctor may interrupt your Tofacitinib 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 Tofacitinib. 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.

Children and adolescents

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

Other medicines and Tofacitinib

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 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 rifampicin, used to treat bacterial infections

- Fluconazole, ketoconazole, 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 tumor necrosis factor, interleukin-17, interleukin-12/interleukin-23, anti-integrins, and strong chemical immunosuppressant including azathioprine, mercaptopurine, ciclosporine, 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 Tofacitinib 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. Tofacitinib must not be used during pregnancy. Tell your doctor right away if you become pregnant while taking tofacitinib.

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

Driving and using machines

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

Tofacitinib contains lactose

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

Tofacitinib contains sodium

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

3. HOW TO TAKE JITRIT

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, 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 twice a day.

Psoriatic arthritis

The recommended dose is 5 mg twice a day.

If you suffer from rheumatoid arthritis or psoriatic arthritis, your doctor may switch your tablets between Tofacitinib 5 mg film-coated tablets twice daily and Tofacitinib 11 mg prolonged-release tablet once daily. You can start the Tofacitinib prolonged-release tablet once daily or Tofacitinib film-coated tablets twice daily on the day following the last dose of either tablet. You should not switch between Tofacitinib film-coated tablets and Tofacitinib prolonged-release tablet unless instructed by your doctor.

Ankylosing spondylitis

- The recommended dose is 5 mg twice a day.
- Your doctor may decide to stop Tofacitinib if Tofacitinib does not work for you within 16 weeks.

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 Tofacitinib if Tofacitinib 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 increase your dose of Tofacitinib to 10 mg twice a day if you do not respond sufficiently to 5 mg twice a day. Your doctor will consider the potential risks, including that of developing blood clots in the lungs or veins, and potential benefits to you. Your doctor will tell you if this applies to you.

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

Use in children and adolescents

Polyarticular juvenile idiopathic arthritis and juvenile psoriatic arthritis

• The recommended dose is 5 mg twice a day for patients ≥40 kg.

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

Tofacitinib tablets may be crushed and taken with water.

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.

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

If you take more Tofacitinib than you should

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

If you forget to take Tofacitinib

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 Tofacitinib

You should not stop taking Tofacitinib 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.

Possible serious side effects

In rare cases, infection may be life-threatening

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

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, 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 (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), 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 Tofacitinib was used alone than in combination with methotrexate in rheumatoid arthritis.

In general, fewer side effects were seen when Tofacitinib was used alone than in combination with methotrexate in rheumatoid arthritis.

5. HOW TO STORE JITRIT

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.

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 discolored).

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 JITRIT contains

Active ingredient: Tofacitinib

Inactive ingredients: Microcrystalline cellulose; Lactose Monohydrate; Croscarmellose Sodium; Magnesium Stearate; Opadry white 03G580003

Ingredients of Opadry white 03G580003:- Hypromellose, Titanium Dioxide, Polyethylene Glycol and Triacetin

What JITRIT looks like and contents of the pack

White to off-white, circular shaped, biconvex film coated tablets debossed with 'TC' on one face and '5' on other face.

4x15’s - Alu/PVC Blister

Manufacturer

MICRO LABS LIMITED

No. 92, Sipcot Industrial Complex

Hosur -635 126 (TN)

INDIA

Marketing Authorisation Holder

MICRO LABS LIMITED

31, Race Course Road
Bangalore 560001
INDIA

Date of Revision

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