Your doctor is the best resource for medical advice and information. The health information contained herein is provided for educational / awareness purposes only and is not intended to replace discussions with a medical practitioner and/or medical advice or be construed as a promotional information.

Package Leaflet: Information for the user

Tofacitinib Film-Coated Tablets 5 mg
BETRECEP®

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- If you have any further questions, ask your doctor.
- 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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What BETRECEP (Tofacitinib) is and what it is used for

BETRECEP (Tofacitinib) is a medicine that contains the active substance tofacitinib.
BETRECEP (Tofacitinib) is used for the treatment of the following inflammatory diseases:

- Rheumatoid arthritis
- Psoriatic arthritis
- Ankylosing spondylitis
- Ulcerative colitis

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Rheumatoid arthritis

BETRECEP (Tofacitinib) is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to methotrexate. It may be used as monotherapy or in combination with methotrexate or other nonbiologic disease-modifying antirheumatic drugs (DMARDs).

- Limitations of Use: Use of BETRECEP (Tofacitinib) in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

Psoriatic arthritis

BETRECEP (Tofacitinib) is indicated for the treatment of adult patients with active psoriatic arthritis (PsA) who have had an inadequate response or intolerance to methotrexate or other non-biologic disease-modifying antirheumatic drugs (DMARDs).

- Limitations of Use: Use of BETRECEP (Tofacitinib) in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

Ankylosing spondylitis

BETRECEP (Tofacitinib) is indicated for the treatment of adult patients with active ankylosing spondylitis (AS) who have responded inadequately to conventional therapy.

- Limitations of Use: Use of BETRECEP (Tofacitinib) in combination with biologic DMARDs or potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

Ulcerative colitis

BETRECEP (Tofacitinib) is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis (UC), who have an inadequate response and who are intolerant to TNF blockers.

- Limitations of Use: Use of BETRECEP (Tofacitinib) in combination with biological therapies for UC or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

2. What you need to know before you take BETRECEP (Tofacitinib)

Do not take BETRECEP (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 before taking BETRECEP (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. BETRECEP (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 BETRECEP (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 BETRECEP (Tofacitinib). Your doctor may do blood tests for hepatitis before you start treatment with BETRECEP (Tofacitinib) and while you are taking BETRECEP (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. BETRECEP (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 BETRECEP (Tofacitinib). If you develop cancer while taking BETRECEP (Tofacitinib) your doctor will review whether to stop BETRECEP (Tofacitinib) treatment.
- If you are at high risk of developing skin cancer, your doctor may recommend that you have regular skin examinations while taking BETRECEP (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 BETRECEP (Tofacitinib). Before you start BETRECEP (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, high cholesterol, and also if you are a current or past smoker.

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

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

Your doctor may decide that BETRECEP (Tofacitinib) is not suitable for you.

Other medicines and BETRECEP (Tofacitinib)

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

Some medicines should not be taken with BETRECEP (Tofacitinib). If taken with BETRECEP (Tofacitinib), they could alter the level of BETRECEP (Tofacitinib) in your body, and the dose of BETRECEP (Tofacitinib) may require adjustment. You should tell your doctor if you are using medicines that contain any of the following active substances:

- Antibiotics such as rifampicin, used to treat bacterial infections
- Fluconazole, ketoconazole, used to treat fungal infections

BETRECEP (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 immunosuppressants including azathioprine, ciclosporin, and tacrolimus. Taking BETRECEP (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 BETRECEP (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. BETRECEP (Tofacitinib) must not be used during pregnancy. Tell your doctor right away if you become pregnant while taking BETRECEP (Tofacitinib).

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

Driving and using machines

No formal studies have been conducted on the effects on the ability to drive and use machines.

3. How to take BETRECEP (Tofacitinib)

Always take this medicine exactly as your doctor has told you, the recommended dose should not be exceeded. Check with your doctor 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.

Ankylosing spondylitis

- 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 BETRECEP (Tofacitinib) if BETRECEP (Tofacitinib) does not work for you within 16 weeks.
- For patients who have previously taken biologic medicines to treat ulcerative colitis with loss of response during maintenance treatment, a dosage of 10 mg twice daily may be considered and limited to the shortest duration, with careful consideration of the benefits and risks for the individual patient. Use the lowest effective dose needed to maintain response.

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.

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

If you take more BETRECEP (Tofacitinib) than you should

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

If you forget to take BETRECEP (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 BETRECEP (Tofacitinib)

You should not stop taking BETRECEP (Tofacitinib) without discussing this with your doctor.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Common side effects:

- Lung infection (pneumonia)
- Shingles (herpes zoster)
- Infections of nose, throat or the windpipe (nasopharyngitis), sinusitis
- Urinary bladder infection
- Sore throat (pharyngitis)
- Stomach (belly) pain (which may be from inflammation of the stomach lining)
- Vomiting
- Diarrhoea
- Headache
- Feeling sick (nausea)
- Swelling of the feet and hand
- High blood pressure (hypertension)
- Slurred speech
- Cough.
- Acne

Other side effects:

- Fever
- Fatigue
- Rash, skin redness, itching
- Anemia
- Skin infection
- Herpes simplex or cold sores (oral herpes)
- Low white blood cell counts
- Increased liver enzymes in the blood (sign of liver problems), hepatic steatosis
- Blood creatinine increased (a possible sign of kidney problems)
- Increased cholesterol (including increased LDL)
- Dehydration
- Cold sweat
- light headedness or sudden dizziness
- Muscle strain, pain in the muscles and joints, tendonitis, joint swelling, joint sprain
- Poor sleep
- Shortness of breath or difficulty breathing
- 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).

5. How to store BETRECEP (Tofacitinib)

Store below 30°C
This medicine does not require any special temperature storage conditions.

6. Contents of the pack and other information

What BETRECEP (Tofacitinib) contains

- The active substance is tofacitinib.
- Each 5 mg film-coated tablet contains 8.078 mg of tofacitinib citrate equivalent to 5 mg of tofacitinib free base active pharmaceutical ingredient.
- The other ingredients are microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, magnesium stearate.
- For film coat for 5 mg Tablets - Opadry® II White (33G28523) containing: HPMC 2910/Hypromellose 6cP (E464), Titanium Dioxide (E171), Lactose Monohydrate, Macrogol/PEG3350, Triacetin (Glycerol Triacetate).

What BETRECEP (Tofacitinib) looks like and contents of the pack

BETRECEP (Tofacitinib) 5 mg film-coated tablet is white, round, immediate-release film-coated tablets for oral use, embossed with “Pfizer” on one side, and plain on the other side.

4 Foil/foil blisters containing 14 film-coated tablets each per pack.

Not all pack sizes may be marketed.

Imported and marketed by

Pfizer Limited, The Capital - A Wing, 1802, 18th Floor Plot No. C-70, G Block, Bandra Kurla Complex, Bandra (East), Mumbai 400 051, India.

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