For the use only of Registered Medical Practitioner

1. Generic Name & Brand Name

Tofacitinib Tablets I.P. 5 mg
TACITINIX™

WARNING: SERIOUS INFECTIONS, MORTALITY, MALIGNANCY, MAJOR ADVERSE CARDIOVASCULAR EVENTS (MACE), AND THROMBOSIS

See full prescribing information for complete boxed warning.

- Increased risk of serious bacterial, fungal, viral, and opportunistic infections leading to hospitalization or death, including tuberculosis (TB). Interrupt treatment with TACITINIX if serious infection occurs until the infection is controlled. Test for latent TB before and during therapy; treat latent TB prior to use. Monitor all patients for active TB during treatment, even patients with initial negative latent TB test.
- Higher rate of all-cause mortality, including sudden cardiovascular death with TACITINIX vs. TNF blockers in rheumatoid arthritis (RA) patients.
- Malignancies have occurred in patients treated with TACITINIX. Higher rate of lymphomas and lung cancers with TACITINIX vs. TNF blockers in RA patients.
- Higher rate of MACE (defined as cardiovascular death, myocardial infarction, and stroke) with TACITINIX vs. TNF blockers in RA patients.
- Thrombosis has occurred in patients treated with TACITINIX. Increased incidence of pulmonary embolism, venous and arterial thrombosis with TACITINIX vs. TNF blockers in RA patients.

2. Qualitative and Quantitative Composition:

Each Film Coated Tablet contains:
Tofacitinib Citrate I.P.
Equivalent to Tofacitinib 5 mg
Colour: Titanium Dioxide I.P.

3. Dosage Form & strength

Refer section 1 & 2

4. Clinical particulars

4.1 Therapeutic indication

For the treatment of adult patients with moderately to severely active rheumatoid arthritis 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).

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)

4.2 Posology and method of administration

Posology: The recommended dose in Rheumatoid arthritis is 1 tablet twice a day or as directed by the physician. Recommended dosage in patients with moderate and severe renal impairment or moderate hepatic impairment is Tacitinix 5 mg once daily.

Psoriatic Arthritis: Tacitinix 5 mg twice daily
Recommended dosage in patients with moderate and severe renal impairment or moderate hepatic impairment is Tacitinix 5 mg once daily.

Limitations of Use: Use of Tacitinix in combination with biologic DMARDs or potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

Method of Administration: : For oral use only.

4.3 Contraindications
Hypersensitivity to the active substance or to any of the excipients.
• Active tuberculosis (TB), serious infections such as sepsis, or opportunistic infections
• Severe hepatic impairment
• Pregnancy and lactation

4.4 Special warnings and precautions for use
General
Use in patients over 65 years of age
Considering the increased risk of serious infections, myocardial infarction, and malignancies with tofacitinib in patients over 65 years of age, tofacitinib should only be used in these patients if no suitable treatment alternatives are available.
Serious infections
Serious and sometimes fatal infections due to bacterial, mycobacterial, invasive fungal, viral, or other opportunistic pathogens have been reported in patients receiving tofacitinib. The risk of opportunistic infections is higher in Asian geographic regions. Rheumatoid arthritis patients taking corticosteroids may be predisposed to infection. Tofacitinib should not be initiated in patients with active infections, including localised infections.
- The risks and benefits of treatment should be considered prior to initiating tofacitinib in patients:
- with recurrent infections,
- with a history of a serious or an opportunistic infection
- who have resided or travelled in areas of endemic mycoses,
- who have underlying conditions that may predispose them to infection.

Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with tofacitinib. Treatment should be interrupted if a patient develops a serious infection, an opportunistic infection, or sepsis. A patient who develops a new infection during treatment with tofacitinib should undergo prompt and complete diagnostic testing appropriate for an immunocompromised patient, appropriate antimicrobial therapy should be initiated, and the patient should be closely monitored. As there is a higher incidence of infections

in the elderly and in the diabetic populations in general, caution should be used when treating the elderly and patients with diabetes. In patients over 65 years of age tofacitinib should only be used if no suitable treatment alternatives are available. Risk of infection may be higher with increasing degrees of lymphopenia and consideration should be given to lymphocyte counts when assessing individual patient risk of infection.

Tuberculosis

The risks and benefits of treatment should be considered prior to initiating tofacitinib in patients:

- who have been exposed to TB,
- who have resided or travelled in areas of endemic TB. Patients should be evaluated and tested for latent or active infection prior to and per applicable guidelines during administration of tofacitinib. Patients with latent TB, who test positive, should be treated with standard antimycobacterial therapy before administering tofacitinib. Antituberculosis therapy should also be considered prior to administration of tofacitinib in patients who test negative for TB but who have a past history of latent or active TB and where an adequate course of treatment cannot be confirmed; or those who test negative but who have risk factors for TB infection. Consultation with a healthcare professional with expertise in the treatment of TB is recommended to aid in the decision about whether initiating antituberculosis therapy is appropriate for an individual patient. Patients should be closely monitored for the development of signs and symptoms of TB, including patients who tested negative for latent TB infection prior to initiating therapy. Gastrointestinal perforations Events of gastrointestinal perforation have been reported in clinical trials although the role of JAK inhibition in these events is not known. Tofacitinib should be used with caution in patients who may be at increased risk for gastrointestinal perforation (e.g., patients with a history of diverticulitis, patients with concomitant use of corticosteroids and/or nonsteroidal anti-inflammatory drugs). Patients presenting with new onset abdominal signs and symptoms should be evaluated promptly for early identification of gastrointestinal perforation.

Hypersensitivity

In post-marketing experience, cases of drug hypersensitivity associated with tofacitinib administration have been reported. Allergic reactions included angioedema and urticaria; serious reactions have occurred. If any serious allergic or anaphylactic reaction occurs, tofacitinib should be discontinued immediately.

Vaccinations

Prior to initiating tofacitinib, it is recommended that all patients be brought up to date with all immunisations in agreement with current immunisation guidelines. It is recommended that live vaccines not be given concurrently with tofacitinib. The decision to use live vaccines prior to tofacitinib treatment should take into account the pre-existing immunosuppression in a given patient. Prophylactic zoster vaccination should be considered in accordance with vaccination guidelines. Particular consideration should be given to patients with longstanding RA who have previously received two or more biological DMARDs. If live zoster vaccine is administered; it should only be administered to patients with a known history of chickenpox or those that are seropositive for varicella zoster virus (VZV). If the history of chickenpox is considered doubtful or unreliable it is recommended to test for antibodies against VZV. Vaccination with live vaccines should occur at least 2 weeks but preferably 4 weeks prior to initiation of tofacitinib or in accordance with current vaccination guidelines regarding immunomodulatory medicinal products.

No data are available on the secondary transmission of infection by live vaccines to patients receiving tofacitinib.
Tofacitinib should only be used if no suitable treatment alternatives are available in patients with history of atherosclerotic cardiovascular disease or other cardiovascular risk factors (such as current or past long-time smokers)
An increased incidence of major adverse cardiovascular events (MACE) & Venous thromboembolism (VTE)
The incidence of non-melanoma skin cancer in the study was also higher with tofacitinib than with a TNF inhibitor.

4.5 Drug Interactions

Potential for other medicinal products to influence the pharmacokinetics (PK) of tofacitinib
Since tofacitinib is metabolised by CYP3A4, interaction with medicinal products that inhibit or induce CYP3A4 is likely. Tofacitinib exposure is increased when coadministered with potent inhibitors of CYP3A4 (e.g., ketoconazole) or when administration of one or more concomitant medicinal products results in both moderate inhibition of CYP3A4 and potent inhibition of CYP2C19. Tofacitinib exposure is decreased when coadministered with potent CYP inducers (e.g., rifampicin). Inhibitors of CYP2C19 alone or P-glycoprotein are unlikely to significantly alter the PK of tofacitinib. Coadministration with ketoconazole (strong CYP3A4 inhibitor), fluconazole (moderate CYP3A4 and potent CYP2C19 inhibitor), tacrolimus (mild CYP3A4 inhibitor) and ciclosporine (moderate CYP3A4 inhibitor) increased tofacitinib AUC, while rifampicin (potent CYP inducer) decreased tofacitinib AUC. Coadministration of tofacitinib with potent CYP inducers (e.g., rifampicin) may result in a loss of or reduced clinical response. Coadministration of potent inducers of CYP3A4 with tofacitinib is not recommended. Coadministration with ketoconazole and fluconazole increased tofacitinib Cmax, while tacrolimus, ciclosporine and rifampicin decreased tofacitinib Cmax . Concomitant administration with MTX 15-25 mg once weekly had no effect on the PK of tofacitinib in RA patients.
Potential for tofacitinib to influence the PK of other medicinal products
Coadministration of tofacitinib did not have an effect on the PK of oral contraceptives, levonorgestrel and ethinyl estradiol, in healthy female volunteers. In RA patients, coadministration of tofacitinib with MTX 15-25 mg once weekly decreased the AUC and Cmax of MTX by 10% and 13%, respectively. The extent of decrease in MTX exposure does not warrant modifications to the individualised dosing of MTX.

4.6 Use in special populations (Pregnancy, Nursing woman, Pediatric use, Geriatric use)
Pregnancy:

There are no adequate and well-controlled studies on the use of tofacitinib in pregnant women. Tofacitinib has been shown to be teratogenic in rats and rabbits, and to affect parturition and peri/postnatal development. As a precautionary measure, the use of tofacitinib during pregnancy is contraindicated.

Women of childbearing potential/contraception in females:

Women of childbearing potential should be advised to use effective contraception during treatment with tofacitinib and for at least 4 weeks after the last dose.

Breast-feeding:

It is not known whether tofacitinib is secreted in human milk. A risk to the breast-fed child cannot be excluded. Tofacitinib was secreted in the milk of lactating rats (see section 5.3). As a precautionary measure, the use of tofacitinib during breast-feeding is contraindicated.

Fertility:

Formal studies of the potential effect on human fertility have not been conducted. Tofacitinib impaired female fertility but not male fertility in rats.

4.7 Effects on ability to drive and use machines
Tofacitinib has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects
Summary of the safety profile
Rheumatoid arthritis
The most common serious adverse reactions were serious infections In the long-term safety all exposure population, the most common serious infections reported with tofacitinib were pneumonia (1.7%), herpes zoster (0.6%), urinary tract infection (0.4%), cellulitis (0.4%), diverticulitis (0.3%), and appendicitis (0.2%). Among opportunistic infections, TB and other mycobacterial infections, cryptococcus, histoplasmosis, oesophageal candidiasis, multidermatomal herpes zoster, cytomegalovirus, BK virus infections and listeriosis were reported with tofacitinib. Some patients have presented with disseminated rather than localised disease. Other serious infections that were not reported in clinical studies may also occur (e.g., coccidioidomycosis). The most commonly reported adverse reactions during the first 3 months of the double-blind, placebo or MTX controlled clinical trials were headache (3.9%), upper respiratory tract infections (3.8%), viral upper respiratory tract infection (3.3%), diarrhoea (2.9%), nausea (2.7%), and hypertension (2.2%).
The proportion of patients who discontinued treatment due to adverse reactions during first 3 months of the double-blind, placebo or MTX controlled studies was 3.8% for patients taking tofacitinib. The most common infections resulting in discontinuation of therapy during the first 3 months in controlled clinical trials were herpes zoster (0.19%) and pneumonia (0.15%).
Psoriatic arthritis Overall, the safety profile observed in patients with active PsA treated with tofacitinib was consistent with the safety profile observed in patients with RA treated with tofacitinib.

4.9 Overdose

In case of an overdose, it is recommended that the patient be monitored for signs and symptoms of adverse reactions. There is no specific antidote for overdose with tofacitinib. Treatment should be symptomatic and supportive. Pharmacokinetic data up to and including a single dose of 100 mg in healthy volunteers indicate that more than 95% of the administered dose is expected to be eliminated within 24 hours.

5. Pharmacological properties

5.1 Mechanism of action

Tofacitinib is a potent, selective inhibitor of the JAK family. In enzymatic assays, tofacitinib inhibits JAK1, JAK2, JAK3, and to a lesser extent TyK2. In contrast, tofacitinib has a high degree of selectivity against other kinases in the human genome. In human cells, tofacitinib preferentially inhibits signalling by heterodimeric cytokine receptors that associate with JAK3 and/or JAK1 with functional selectivity over cytokine receptors that signal via pairs of JAK2. Inhibition of JAK1 and JAK3 by tofacitinib attenuates signalling of interleukins (IL-2, -4, -6, -7, -9, -15, -21) and type I and type II interferons, which will result in modulation of the immune and inflammatory response.

5.2 Pharmacodynamic Properties

In patients with RA, treatment up to 6 months with tofacitinib was associated with dose-dependent reductions of circulating CD16/56+ natural killer (NK) cells, with estimated maximum reductions occurring at approximately 8-10 weeks after initiation of therapy. These changes generally resolved within 2-6 weeks after discontinuation of treatment. Treatment with tofacitinib was associated with dose-dependent increases in B cell counts. Changes in circulating T-lymphocyte counts and T-lymphocyte subsets (CD3+, CD4+ and CD8+) were small and inconsistent. Following long-term treatment (median duration of tofacitinib treatment of approximately 5 years), CD4+ and CD8+ counts showed median reductions of 28% and 27%, respectively, from baseline. In contrast to the observed decrease after short-term dosing, CD16/56+ natural killer cell counts showed a median increase of 73% from baseline. CD19+ B cell counts showed no further increases after long-term tofacitinib treatment. All these lymphocyte subset changes returned toward baseline after temporary discontinuation of treatment. There was no evidence of a relationship between serious or opportunistic infections or herpes zoster and lymphocyte subset counts. Changes in total serum IgG, IgM, and IgA levels over 6-month tofacitinib dosing in patients with RA were small, not dose-dependent and similar to those seen on placebo, indicating a lack of systemic humoral suppression. After treatment with tofacitinib in RA patients, rapid decreases in serum C-reactive protein (CRP) were observed and maintained throughout dosing. Changes in CRP observed with tofacitinib treatment do not reverse fully within 2 weeks after discontinuation, indicating a longer duration of pharmacodynamic activity compared to the half-life.

5.3 Pharmacokinetic properties

The PK profile of tofacitinib is characterised by rapid absorption (peak plasma concentrations are reached within 0.5-1 hour), rapid elimination (half-life of ~3 hours) and dose-proportional increases in systemic exposure. Steady state concentrations are achieved in 24-48 hours with negligible accumulation after twice daily administration.

Absorption and distribution

Co-administration of tofacitinib 5 mg tablet with a high-fat meal resulted in no changes in AUC while Cmax was increased by 27%. After intravenous administration, the volume of distribution is 87 L. Approximately 40% of circulating tofacitinib is bound to plasma proteins. Tofacitinib binds predominantly to albumin and does not appear to bind to α1-acid glycoprotein. Tofacitinib distributes equally between red blood cells and plasma.

Biotransformation and elimination

Clearance mechanisms for tofacitinib are approximately 70% hepatic metabolism and 30% renal excretion of the parent drug. The metabolism of tofacitinib is primarily mediated by CYP3A4 with minor contribution from CYP2C19. In a human radiolabelled study, more than 65% of the total circulating radioactivity was accounted for by unchanged active substance, with the remaining 35% attributed to 8 metabolites, each accounting for less than 8% of total radioactivity. All metabolites have been observed in animal species and are predicted to have less than 10-fold potency than tofacitinib for JAK1/3 inhibition. No evidence of stereo conversion in human samples was detected. The pharmacologic activity of tofacitinib is attributed to the parent molecule. In vitro, tofacitinib is a substrate for MDR1, but not for breast cancer resistance protein (BCRP), OATP1B1/1B3, or OCT1/2.

6. Nonclinical properties

6.1 Animal Toxicology or Pharmacology

In non-clinical studies, effects were observed on the immune and haematopoietic systems that were attributed to the pharmacological properties (JAK inhibition) of tofacitinib. Secondary effects from immunosuppression, such as bacterial and viral infections and lymphoma were observed at clinically relevant doses. Lymphoma was observed in 3 of 8 adult monkeys at 6 or 3 times the clinical tofacitinib exposure level (unbound AUC in humans at a dose of 5 mg or 10 mg twice daily), and 0 of 14 juvenile monkeys at 5 or 2.5 times the clinical exposure level of 5 mg or 10 mg twice daily. Exposure in monkeys at the no observed adverse effect level (NOAEL) for the lymphomas was approximately 1 or 0.5 times the clinical exposure level of 5 mg or 10 mg twice daily. Other findings at doses exceeding human exposures included effects on the hepatic and gastrointestinal systems. Tofacitinib is not mutagenic or genotoxic based on the results of a series of *in vitro* and *in vivo* tests for gene mutations and chromosomal aberrations. The carcinogenic potential of tofacitinib was assessed in 6-month rasH2 transgenic mouse carcinogenicity and 2-year rat carcinogenicity studies. Tofacitinib was not carcinogenic in mice at exposures up to 38 or 19 times the clinical exposure level at 5 mg or 10 mg twice daily. Benign testicular interstitial (Leydig) cell tumours were observed in rats: benign Leydig cell tumours in rats are not associated with a risk of Leydig cell tumours in humans. Hibernomas (malignancy of brown adipose tissue) were observed in female rats at exposures greater than or equal to 83 or 41 times the clinical exposure level at 5 mg or 10 mg twice daily. Benign thymomas were observed in female rats at 187 or 94 times the clinical exposure level at 5 mg or 10 mg twice daily.

Tofacitinib was shown to be teratogenic in rats and rabbits, and have effects in rats on female fertility (decreased pregnancy rate; decreases in the numbers of corpora lutea, implantation sites,

and viable foetuses; and an increase in early resorptions), parturition, and peri/postnatal development. Tofacitinib had no effects on male fertility, sperm motility or sperm concentration. Tofacitinib was secreted in milk of lactating rats at concentrations approximately 2-fold those in serum from 1 to 8 hours postdose. In studies conducted in juvenile rats and monkeys, there were no tofacitinib-related effects on bone development in males or females, at exposures similar to those achieved at approved doses in humans.

No tofacitinib-related findings were observed in juvenile animal studies that indicate a higher sensitivity of paediatric populations compared with adults. In the juvenile rat fertility study, there was no evidence of developmental toxicity, no effects on sexual maturation, and no evidence of reproductive toxicity (mating and fertility) was noted after sexual maturity. In 1-month juvenile rat and 39-week juvenile monkey studies tofacitinib-related effects on immune and haematology parameters consistent with JAK1/3 and JAK2 inhibition were observed. These effects were reversible and consistent with those also observed in adult animals at similar exposures.

7. Description

Tacitinix is supplied for oral administration, as a Film Coated Tablet of Tofacitinib Citrate. Each Film Coated Tablet of Tacitinix contains Tofacitinib Citrate equivalent to Tofacitinib 5 mg.

8. Pharmaceutical particulars

8.1 Incompatibilities

Not applicable

8.2 Shelf Life

Refer Pack

8.3 Packaging Information

Refer Pack

8.4 Storage condition & handling instructions

Refer Pack

9. Patient Counseling Information

Read this entire leaflet carefully before you start 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.

What Tofacitinib Tablets is and what it is used for?

It is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis 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.

What you need to know before you use Tablets
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
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 65 years of age and older, 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, skin, 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 known risk of fractures, e.g., if you are 65 years of age and older, you are a female, or take corticosteroids (e.g., prednisone).
• Cases of non-melanoma skin cancer have been observed in patients taking Tofacitinib. Your doctor may recommend that you have regular skin examinations while taking Tofacitinib. If new skin lesions appear during or after therapy or if existing lesions change appearance, tell your doctor.
• 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 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, high cholesterol, and also if you are a current or past smoker

Children and adolescents

The safety and benefits of Tofacitinib in children have not yet been established in patients less than 2 years of age.

Other medicines and Tofacitinib Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Tell your doctor if you have diabetes or are taking medicines to treat diabetes. Your doctor may decide if you need less anti-diabetic medicine while taking tofacitinib. 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 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 tumour necrosis factor, interleukin-17, interleukin-12/interleukin-23, anti-integrins, and strong chemical immunosuppressants including azathioprine, mercaptopurine, ciclosporin, and tacrolimus. Taking Tofacitinib with these medicines may increase your risk of side effects including infection. Serious infections and fractures 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.

How to take Tofacitinib Tablets?

Posology

The recommended dose is 1 tablet twice a day or as directed by the physician.

Method of administration: For oral use only.

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. Side effects in patients with polyarticular juvenile idiopathic arthritis and juvenile psoriatic arthritis were consistent with those seen in adult rheumatoid arthritis patients with the exception of some infections (influenza, pharyngitis, sinusitis, viral infection) and gastrointestinal or general disorders (abdominal pain, nausea,

vomiting, fever, headache, cough), which were more common in juvenile idiopathic arthritis paediatric population.
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(perforations) 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 or eyes (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
• acute changes in eyesight Signs of a heart attack (uncommon) include
• severe chest pain or tightness (that may spread to arms, jaw, neck, back)
• shortness of breath
• cold sweat
• light headedness or sudden dizziness
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 enzymesin 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 white blood cell counts, low red blood cell count (anaemia), swelling of the feet and hands, headache, high blood pressure (hypertension), cough, rash.
Uncommon (may affect up to 1 in 100 people): lung cancer, tuberculosis, kidney infection, skin infection, herpes simplex or cold sores (oral herpes), blood creatinine increased (a possible sign of kidney problems), increased cholesterol (including increased LDL), fever, fatigue (tiredness),

weight gain, dehydration, muscle strain, 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), lymphoma (white blood cell cancer), disseminated tuberculosis involving bones and other organs, other unusual infections, joint infections, increased liver enzymes in the blood (sign of liver problems), pain in the muscles and joints.
Very rare (may affect up to 1 in 10,000 people): tuberculosis involving the brain and spinal cord, meningitis, infection of the soft tissue and fascia. In general, fewer side effects were seen when Tofacitinib was used alone than in combination with methotrexate in rheumatoid arthritis.

10. Details of manufacturer
Refer Pack for manufacturer details.

Marketed by:
Abbott Healthcare Pvt. Ltd.
Angel Space, Bldg. D-4, Gala No. 1 to 3 &
11 to 13 Ground Floor, 101 to 106 &
111 to 116 First Floor, 201 to 206 & 211 to 216
2nd Floor, Pimplas, Dist. Thane, Bhiwandi - 421 302,
Maharashtra, India.
TM – Trade Mark of Abbott Healthcare Pvt. Ltd.

11. Details of permission or licence number
Refer Pack for Permission/License details

12. Date of revision
Version 3.0, dated 23-Mar-26

For Product Complaints/Adverse events or Queries please write to **webmasterindia@abbott.com**