Package leaflet: Information for the patient

Tofacitinib Teva 5 mg film-coated tablets
Tofacitinib Teva 10 mg film-coated tablets

tofacitinib

Read all of this 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. See section 4.

In addition to this leaflet, your doctor will also give you a Patient Alert Card, which contains important safety information that you need to be aware of before you are given Tofacitinib Teva and during treatment with this medicine. Keep this Patient Alert Card with you.

What is in this leaflet

1. What Tofacitinib Teva is and what it is used for
2. What you need to know before you take Tofacitinib Teva
3. How to take Tofacitinib Teva
4. Possible side effects
5. How to store Tofacitinib Teva
6. Contents of the pack and other information

1. What Tofacitinib Teva is and what it is used for

Tofacitinib Teva is a medicine that contains the active substance tofacitinib.

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

Tofacitinib Teva 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 Teva is used to treat adult patients with 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 to reduce the sign and symptoms of active psoriatic arthritis and improve the ability to perform daily activities.

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

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

If you have ankylosing spondylitis, you may first be given other medicines. If you do not respond well enough to these medicines, you will be given Tofacitinib Teva. Tofacitinib Teva can help to reduce back pain and improve physical function. These effects can ease your normal daily activities and so improve your quality of life.

Ulcerative colitis
Ulcerative colitis is an inflammatory disease of the large bowel. Tofacitinib Teva is used in adult patients 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 Teva 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 Teva 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 Teva 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 Teva 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 Tofacitinib Teva

Do not take Tofacitinib Teva
- 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 Teva:
- 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 Teva 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 Teva 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 Teva. Your doctor may do blood tests for hepatitis before you start treatment with Tofacitinib Teva and while you are taking this medicine
- 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 Teva 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 Teva. If you develop cancer while taking this medicine, your doctor will review whether to stop Tofacitinib Teva 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 Teva. Your doctor may recommend that you have regular skin examinations while taking this medicine. 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** (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 this medicine. Before you start Tofacitinib Teva, 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 Tofacitinib Teva 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 Teva 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 Tofacitinib Teva 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 this medicine, as these may be signs of a clot in the lungs or veins.
- if you experience **acute changes to your eyesight** (blurry vision, partial or complete loss of vision), as this may be a sign of blood clots in the eyes.
- if you, your partner or your caregiver notice **new onset of severe headaches**, which can be accompanied by nausea and vomiting, **fainting, dizziness or light headedness, temporary vision problems, weakness on one side of the body, progressive decline in mental status, seizures, or loss of consciousness**, as these may be a sign of blood clots in veins around the brain.
- 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. There have been reports of patients treated with Tofacitinib Teva who have had a heart problem, including heart attack. Your doctor will evaluate your risk to develop a heart problem and determine if Tofacitinib Teva is appropriate for you.
- if you, your partner or your caregiver notice new onset or worsening of neurological symptoms including general muscle weakness, disturbance of vision, changes in thinking, memory and orientation leading to confusion and personality changes contact your doctor immediately because these may be symptoms of a very rare, serious brain infection called progressive multifocal leukoencephalopathy (PML).

<u>Additional monitoring tests</u>

Your doctor should perform blood tests before you start taking Tofacitinib Teva, 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 Teva 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 Teva 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 Teva. Your doctor should perform liver tests periodically.

Elderly
There is a higher rate of infections, some of which may be serious, in patients 65 years of age and older. Tell your doctor as soon as you notice any signs or symptoms of infections.

Patients 65 years of age and older may be at increased risk of infections, heart attack and some types of cancer. Your doctor may decide that Tofacitinib Teva is not suitable for you.

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

Other medicines and Tofacitinib Teva
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 Teva**. If taken with Tofacitinib Teva, they could alter the level of Tofacitinib Teva in your body, and the dose of Tofacitinib Teva 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 Teva 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 Teva 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 Teva 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 Teva must not be used during pregnancy. Tell your doctor right away if you become pregnant while taking Tofacitinib Teva.

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

Driving and using machines
Tofacitinib Teva has no or limited effect on your ability to drive or use machines.

Tofacitinib Teva 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.

Tofacitinib Teva contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How to take Tofacitinib Teva

This medicine is provided to you and supervised by a specialised 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 Teva 5 mg film-coated tablets twice daily and tofacitinib-containing medicinal products available as 11 mg prolonged-release tablet once daily. You can start the prolonged-release tablet once daily or Tofacitinib Teva film-coated tablets twice daily on the day following the last dose of either tablet. You should not switch between Tofacitinib Teva film-coated tablets and prolonged-release tablets unless instructed by your doctor.

Ankylosing spondylitis
- The recommended dose is 5 mg twice a day.
- Your doctor may decide to stop Tofacitinib Teva if Tofacitinib Teva 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 Teva if Tofacitinib Teva 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 Teva 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 Teva is for oral use. You can take Tofacitinib Teva with or without food.

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

If you forget to take Tofacitinib Teva
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 Teva
You should not stop taking Tofacitinib Teva 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.

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.

Possible serious side effects
In rare cases, infection may be life-threatening. Lung cancer, white blood cell cancer and heart attack have also been reported.

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
- new onset of severe headaches
- fainting, dizziness or light headedness
- weakness on one side of the body, progressive decline in mental status, seizures, or loss of consciousness

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 Teva 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 white blood cell counts, low red blood cell count (anaemia), swelling of the feet and hands, headache, high blood pressure (hypertension), cough, rash, acne.

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 Teva was used alone than in combination with methotrexate in rheumatoid arthritis.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tofacitinib Teva

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 carton, bottle and blister after 'EXP'. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Bottle:
Use within 6 months from first opening.

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 Tofacitinib Teva contains

Tofacitinib Teva 5 mg film-coated tablet
- The active substance is tofacitinib.
- Each 5 mg film-coated tablet contains 5 mg of tofacitinib (as tofacitinib citrate).
- The other ingredients are microcrystalline cellulose, lactose monohydrate (see section 2 "Tofacitinib Teva contains lactose"), croscarmellose sodium (see section 2 "Tofacitinib Teva contains sodium"), magnesium stearate, hypromellose (E464), titanium dioxide (E171), macrogol (E1521).

Tofacitinib Teva 10 mg film-coated tablet
- The active substance is tofacitinib.
- Each 10 mg film-coated tablet contains 10 mg of tofacitinib (as tofacitinib citrate).
- The other ingredients are microcrystalline cellulose, lactose monohydrate (see section 2 "Tofacitinib Teva contains lactose"), croscarmellose sodium (see section 2 "Tofacitinib Teva contains sodium"), magnesium stearate, hypromellose (E464), titanium dioxide (E171), macrogol (E1521), indigo carmine aluminum lake (E132).

What Tofacitinib Teva looks like and contents of the pack

Tofacitinib Teva 5 mg film-coated tablets are white, round, film-coated tablets, approximately 8 mm in diameter, debossed with ″TV″ on one side, and ″E71″on the other side.

Tofacitinib Teva 10 mg film-coated tablets are blue, round, film-coated tablets, approximately 10 mm in diameter, debossed with ″TV″ on one side, and ″E77″on the other side.

Tofacitinib Teva is supplied in the following pack sizes:

Tofacitinib Teva 5 mg film-coated tablets are available in OPA/Al/PVC//Al blisters containing 56, 112 or 182 tablets, unit dose blisters containing 56 x 1, 112 x 1 or 182 x 1 film-coated tablets or HDPE bottles containing 180 film-coated tablets.

Tofacitinib Teva 10 mg film-coated tablets are available in OPA/Al/PVC//Al blisters containing 56, 112 or 182 tablets, unit dose blisters containing 56 x 1, 112 x 1 or 182 x 1 film-coated tablets or HDPE bottles containing 180 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

TEVA B.V.,
Swensweg 5,
2031GA Haarlem,
The Netherlands

Manufacturer

PLIVA Croatia Ltd.
Prilaz baruna Filipovica 25,
Zagreb, 10 000
Croatia

This medicine is authorised in the Member States of the European Economic Area under the following names:

Austria	Tofacitinib ratiopharm 5 mg, 10 mg Filmtabletten
Bulgaria	Tofacitinib Teva 5 mg, 10 mg film-coated tablets
Germany	Tofacitinib-ratiopharm 5 mg, 10 mg Filmtabletten
Denmark	Tofacitinib Teva
Finland	Tofacitinib ratiopharm 5 mg, 10 mg tabletti, kalvopäällysteinen
France	TOFACITINIB TEVA 5 mg, 10 mg comprimé pelliculé
Hungary	Tofacitinib Teva 5 mg, 10 mg filmtabletta
Iceland	Tofacitinib Teva
Ireland	Tofacitinib Teva 5 mg, 10 mg film-coated tablets
Italy	Tofacitinib Teva
Netherlands	Tofacitinib Teva 5 mg, 10 mg filmomhulde tabletten
Norway	Tofacitinib Teva
Portugal	Tofacitinib Teva
Romania	Tofacitinib Teva 5 mg, 10 mg comprimate filmate
Sweden	Tofacitinib Teva
Spain	Tofacitinib Teva 5 mg, 10 mg comprimidos recubiertos con película EFG

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