**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 [Product name] and during treatment with [Product name]. Keep this Patient Alert Card with you.

**What is in this leaflet**

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


## 1. What [Product name] is and what it is used for

[Product name] is a medicine that contains the active substance tofacitinib.

[Product name] 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**
[Product name] 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.

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

[Product name] 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**
[Product name] 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 [Product name] to reduce the sign and symptoms of active psoriatic arthritis and improve the ability to perform daily activities.

[Product name] is used together with methotrexate to treat adult patients with active psoriatic arthritis.

**Ankylosing spondylitis**
[Product name] 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 [Product name]. [Product name] 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. [Product name] 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**
[Product name] 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.

[Product name] 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.

[Product name] 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. [Product name] 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 [Product name]

**Do not take [Product name]**
- 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 [Product name]:**
- 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. [Product name] 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 [Product name] 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 [Product name]. Your doctor may do blood tests for hepatitis before you start treatment with [Product name] and while you are taking [Product name]
- 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**. [Product name] 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 [Product name]. If you develop cancer while taking [Product name] your doctor will review whether to stop [Product name] 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 [Product name]. Your doctor may recommend that you have regular skin examinations while taking [Product name]. 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 [Product name]. Before you start [Product name], 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 [Product name] 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 [Product name] 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 [Product name] 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 [Product name], 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 [Product name] who have had a heart problem, including heart attack. Your doctor will evaluate your risk to develop a heart problem and determine if [Product name] 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 [Product name], 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 [Product name] if your white blood cell (neutrophil or lymphocyte) count or red blood cell count is too low. If needed, your doctor may interrupt your [Product name] 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 [Product name]. 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 [Product name] 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 [Product name] in children have not yet been established in patients less than 2 years of age.

**Other medicines and [Product name]**
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 [Product name]**. If taken with [Product name], they could alter the level of [Product name] in your body, and the dose of [Product name] 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

[Product name] 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 [Product name] 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 [Product name] 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. [Product name] must not be used during pregnancy. Tell your doctor right away if you become pregnant while taking [Product name].

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

**Driving and using machines**
[Product name] has no or limited effect on your ability to drive or use machines.

**[Product name] 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.

**[Product name] 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 [Product name]

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 [Product name] 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 [Product name] film-coated tablets twice daily on the day following the last dose of either tablet. You should not switch between [Product name] film-coated tablets and 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 [Product name] if [Product name] 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 [Product name] if [Product name] 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 [Product name] 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.

[Product name] is for oral use. You can take [Product name] with or without food.

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

**If you forget to take [Product name]**
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 [Product name]**
You should not stop taking [Product name] 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 [Product name] 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 [Product name] 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 the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store [Product name]

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 [Product name] contains**

[Product name] 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 "[Product name] contains lactose"), croscarmellose sodium (see section 2 "[Product name] contains sodium"), magnesium stearate, hypromellose (E464), titanium dioxide (E171), macrogol (E1521).

[Product name] 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 "[Product name] contains lactose"), croscarmellose sodium (see section 2 "[Product name] contains sodium"), magnesium stearate, hypromellose (E464), titanium dioxide (E171), macrogol (E1521), indigo carmine aluminum lake (E132).

**What [Product name] looks like and contents of the pack**

[Product name] 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.

[Product name] 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.

[Product name] is supplied in the following pack sizes:

[Product name] 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.

[Product name] 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**

[To be completed nationally]

**Manufacturer**

[To be completed nationally]

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

<{Name of the Member State}><{Name of the medicinal product}>
<{Name of the Member State}><{Name of the medicinal product}>

**This leaflet was last revised in 08 July 2026.**

[To be completed nationally]

<Other sources of information

<Latest approved information [add type of information e.g. product information, educational material, video etc] on this medicine is available by scanning [the QR code][other two-dimensional (2D) bar code][Near-field Communication (NFC)] included in the <PL> <outer carton> with a smartphone/device. The same information is also available on the following URL: [URL to be included] <and the <NCA> website >>