PATIENT INFORMATION LEAFLET

FOR TOFAJAK

SCHEDULING STATUS: **S4**

TOFAJAK 5 mg (5 mg, film-coated tablets)

TOFAJAK 10 mg (10 mg, film-coated tablets)

Tofacitinib

Contains sugar:

Each 5 mg film-coated tablet contains 62,56 mg of lactose monohydrate.

Each 10 mg film-coated tablet contains 125,12 mg of lactose monohydrate.

Read all of this leaflet carefully before you start taking TOFAJAK

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- TOFAJAK has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What TOFAJAK is and what it is used for

TOFAJAK is a medicine that contains the active substance tofacitinib.

TOFAJAK is indicated for the treatment of the following inflammatory diseases:

- rheumatoid arthritis
- psoriatic arthritis
- ulcerative colitis

Rheumatoid arthritis

TOFAJAK 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.

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

TOFAJAK 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

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

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

Ulcerative colitis

Ulcerative colitis is an inflammatory disease of the large bowel. TOFAJAK 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.

2. What you need to know before you take TOFAJAK

Do not take TOFAJAK:

- if you are hypersensitive (allergic) to tofacitinib or any of the other ingredients of TOFAJAK, (listed in **section 6)**,
- if you have a severe infection such as a bloodstream infection or untreated (active or latent) tuberculosis (TB) in the lungs or any other part of the body. If you have latent TB, it means that you do not have active TB but are infected with *Mycobacterium tuberculosis* (bacteria which causes active TB). You may also not feel sick and or have any symptoms If you have latent TB,
- if you have been informed that you have severe liver problems, including cirrhosis (scarring of the liver),
- if you are pregnant or breastfeeding,
- if you have HIV (regardless of whether you are taking medication for it or not).

Don't take TOFAJAK 10 mg twice daily if you have any of the following conditions:

- are taking combined hormonal contraceptives or hormone replacement therapy,
- have heart failure (when the heart does not work as well as it should),
- have had blood clots in the veins,
- have cancer,
- will have or have recently had major surgery,
- inherited coagulation (clotting) disorder.

Warnings and precautions

Take special care with TOFAJAK:

- 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 notice any painful blisters on your skin, tell your doctor,
- 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. TOFAJAK 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 are aged 65 years and older. There is a higher rate of infections in patients in this age group. Tell your doctor as soon as you notice any signs or symptoms of infections,
- 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 TOFAJAK and may retest during treatment,
- tell your doctor if you have or may have HIV infection,
- if you have or had hepatitis B or hepatitis C (viruses that affect the liver). The virus may become active while you are taking TOFAJAK. Your doctor may do blood tests for hepatitis before you start treatment with TOFAJAK and while you are taking TOFAJAK,
- if you have ever had any type of cancer. TOFAJAK may increase your risk of certain cancers. Lymphoma and other cancers (such as lung, breast, melanoma, prostate and pancreatic) have been reported in patients treated with TOFAJAK. If you develop cancer while taking TOFAJAK your doctor will review whether to stop TOFAJAK treatment,
- if you are at high risk of developing skin cancer, your doctor may recommend that you have regular skin examinations while taking TOFAJAK,
- if you suffer from blood clots. There have been reports of patients treated with TOFAJAK who have developed blood clots. Talk to your doctor if you smoke. He/ she will also evaluate whether your body weight, age, or problems being mobile will affect your risk to develop blood clots,
- if you have any chronic lung disease. You may also be at higher risk of certain lung problems. Tell your doctor if you notice any breathing difficulties,
- 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 heart problems, high blood pressure, or high cholesterol,

- if you have liver problems,
- if you have kidney problems.

Additional monitoring tests

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

If you are planning to get vaccinated, tell your doctor. Certain types of vaccines should not be given when taking TOFAJAK. Before you start TOFAJAK, you should be up to date with all recommended vaccinations. Your doctor will decide whether you need to have herpes zoster vaccination.

Children and adolescents

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

Other medicines and TOFAJAK

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines).

TOFAJAK may be used in combination with methotrexate or sometimes alone when used to treat rheumatoid arthritis.
In general, fewer side effects were seen when TOFAJAK was used alone in rheumatoid arthritis.

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

- antibiotics such as rifampicin, used to treat bacterial infections,
- fluconazole, ketoconazole, clotrimazole, itraconazole, and voriconazole, used to treat fungal infections.

TOFAJAK 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 TOFAJAK 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, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking TOFAJAK.

If you are a woman of childbearing age, you should use effective birth control during treatment with TOFAJAK and for at least 4 weeks after the last dose.

TOFAJAK must not be used during pregnancy. Tell your doctor right away if you become pregnant while taking TOFAJAK.

If you are taking TOFAJAK and breastfeeding, you must stop breastfeeding until you talk to your doctor about stopping treatment with TOFAJAK.

Driving and using machines

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

It is not always possible to predict to what extent TOFAJAK may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which TOFAJAK affects you.

TOFAJAK contains lactose monohydrate

TOFAJAK may have an effect on the control of your blood sugar if you have diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking TOFAJAK. Patients with the hereditary conditions of lactose/fructose or galactose intolerance should not take TOFAJAK.

3. How to take TOFAJAK

Do not share medicines prescribed for you with any other person.

Always take TOFAJAK exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure. This medicine is provided to you and supervised by a specialised doctor who knows how to treat your condition.

Rheumatoid arthritis

The recommended dose is 5 mg twice a day.

Psoriatic arthritis

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 TOFAJAK if TOFAJAK 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 continue giving 10 mg twice a day. Your doctor will tell you if this applies to you.
- If maintaining TOFAJAK 5 mg twice a day did not work for you, your doctor may decide to increase the dose to 10 mg twice a day.
- If your treatment is interrupted, your doctor may decide to restart your treatment.

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.

TOFAJAK is for oral use. You can take TOFAJAK with or without food. If you have difficulty swallowing, TOFAJAK tablets may be crushed and taken with water.

Your doctor will tell you how long your treatment with TOFAJAK will last.

Do not stop treatment early if you have the impression that the effect of TOFAJAK is too strong or too weak, tell your doctor or pharmacist.

If you take more TOFAJAK than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take TOFAJAK

Do not take a double dose to make up for forgotten individual doses.

Take your next tablet at the usual time and continue as before.

If you stop taking TOFAJAK

You should not stop taking TOFAJAK 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

TOFAJAK can have side effects.

Not all side effects reported for TOFAJAK are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TOFAJAK, please consult your health care provider for advice.

If any of the following happens, stop taking TOFAJAK and tell your doctor immediately or go to the casualty department at your nearest hospital:

Signs of serious infections include:

- blood infection (sepsis),
- fever and chills,
- cough,

- skin blisters,
- stomach-ache,
- persistent headaches.

Signs of allergic reactions include:

- chest tightness,
- wheezing,
- severe dizziness or light headedness,
- swelling of the lips, tongue or throat,
- hives (itching or skin rash).

Signs of stomach problems (ulcers or holes in your stomach or intestines) 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 non-steroidal anti-inflammatory drugs (NSAIDs) or corticosteroids (e.g. prednisone).

These are all very serious side effects. If you have them, you may have had a serious reaction to TOFAJAK. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Frequent side effects:

- lung infection (pneumonia and bronchitis),
- influenza,
- shingles (herpes zoster),
- urinary bladder infection (cystitis),
- sinusitis,
- infections of nose, throat or the windpipe (nasopharyngitis),
- sore throat (pharyngitis),
- low red blood cell count (anaemia),
- headache,
- high blood pressure (hypertension),
- cough,
- stomach (belly) pain (which may be from inflammation of the stomach lining),
- vomiting,
- diarrhoea,
- feeling sick (nausea),
- indigestion,
- rash,
- joint pain,
- fatigue (tiredness),
- increased muscle enzymes in the blood (sign of muscle problems),
- peripheral oedema (swelling of the leg or arm).

These are all serious side effects. You may need urgent medical attention.

Less frequent side effects:

- tuberculosis,
- painful inflammation of small pockets in the lining of your intestine (diverticulitis),
- kidney infection,
- skin infection,
- herpes simplex or cold sores (oral herpes),
- viral infections,
- viral infections affecting the gut,
- other unusual infections, joint infection,
- disseminated tuberculosis involving bones and other organs,
- tuberculosis involving the brain and spinal cord, meningitis,
- some types of skin cancers (non-melanoma-types),
- low white blood cell counts,
- increased cholesterol,
- dehydration,
- poor sleep,
- abnormal sensations ("pins and needles" sensation),
- shortness of breath or difficulty breathing,
- sinus congestion,
- fatty liver,
- skin redness,

- pruritus (itchy skin),
- pain in the muscles,
- joint swelling,
- tendonitis,
- increased liver enzymes in the blood (sign of liver problems),
- blood creatinine increased (a possible sign of kidney problems),
- increased weight,
- muscle strain,
- ligament sprain.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website, or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free) . By reporting side effects, you can help provide more information on the safety of TOFAJAK.

5. How to store TOFAJAK

- Store at or below 30 ℃.
- Store all medicines out of reach of children.
- Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

- Return all unused medicines to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What TOFAJAK contains

TOFAJAK 5 mg and 10 mg film-coated tablets

The active substance is tofacitinib. Each 5 mg and 10 mg film-coated tablet contains 5 mg and 10 mg of tofacitinib (as tofacitinib citrate) respectively.

The other ingredients are:

Tablet core

TOFAJAK 5 mg and 10 mg film-coated tablets

microcrystalline cellulose

lactose monohydrate

croscarmellose sodium

magnesium stearate

Film coating

TOFAJAK 5 mg: Opadry II complete film coating system 33G28435 white (hypromellose, titanium dioxide, lactose monohydrate, macrogol, triacetin)

TOFAJAK 10 mg: Opadry II complete film coating system 33G90988 blue (hypromellose, titanium dioxide, lactose monohydrate, macrogol, triacetin, indigo carmine aluminium lake (E132), brilliant blue FCF aluminium lake (E133))

What TOFAJAK looks like and contents of the pack

TOFAJAK 5 mg

White to off-white, round, film-coated tablets debossed with “115” on one side and “LP” on the other side.

TOFAJAK 10 mg

Light blue to blue, round, film-coated tablets debossed with “117” on one side and “LP” on the other side.

TOFAJAK is presented:

TOFAJAK 5 mg film-coated tablets are packed in:

- Al-Al blisters. The blisters are packed in carton boxes. (6 blisters x 14 tablets in one carton).
- 40 mL-HDPE bottles with child-resistant PP caps and a desiccant canister (30 or 60 tablets in one bottle).

TOFAJAK 10 mg film-coated tablets are packed in:

- Al-Al blisters. The blisters are packed in carton boxes. (6 blisters x 14 tablets in one carton).
- 60 mL-HDPE bottles with child-resistant PP caps and a desiccant canister (30 or 60 tablets in one bottle).

Not all pack sizes may be marketed.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

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Access to the corresponding Professional Information

To access corresponding Professional Information, scan the QR code below.

PLACE HOLDER: The QR Code to be generated and included after approval.