
TOFACITINIB DEVATIS

Tofacitinib
5 mg Film Coated Tablets

CONSUMER MEDICINE INFORMATION

What is in this leaflet

Please read this leaflet carefully before you start using Tofacitinib Devatis.

This leaflet answers some common questions about Tofacitinib Devatis. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Tofacitinib Devatis against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

This medicine is only available with a doctor's prescription.

What Tofacitinib Devatis is used for

Tofacitinib Devatis contains the active ingredient tofacitinib.

Tofacitinib belongs to a group of medicines called Janus Kinase (JAK) inhibitors. It works by reducing the activity of the enzyme Janus Kinase, which helps to reduce inflammation.

Tofacitinib Devatis 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 Devatis may be used alone or in combination with other oral medicines (such as methotrexate) when used to treat rheumatoid arthritis.

Your doctor may have prescribed Tofacitinib Devatis for another reason.

Ask your doctor if you have any questions about why Tofacitinib Devatis has been prescribed for you.

Before you take Tofacitinib Devatis

When you must not use it

Do not take Tofacitinib Devatis if:

1. you are allergic to tofacitinib, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
2. you are already using a biological (injectable) medicine.
3. you are taking other medicines used to strongly suppress your immune system e.g. azathioprine, 6-mercaptopurine, tacrolimus and cyclosporin
4. you have severe liver problems.

5. the expiry date printed on the pack has passed.
6. the packaging is torn or shows signs of tampering.

If you are not sure whether you should start using Tofacitinib Devatis, talk to your doctor.

Before you start to use it

Tell your doctor if:

- you have allergies to any other medicines, foods, preservatives or dyes
- you have or have had any of the following medical conditions:
 - blood clots in the veins of your legs, arms, or lungs, or clots in the arteries in the past
 - an infection, including localised infection (e.g. a leg ulcer)
 - you are being treated for an infection, get a lot of infections or have infections that keep coming back
 - diabetes, HIV/AIDS, a weak immune system or chronic lung disease. People with these conditions have a higher chance of developing infections.
 - hepatitis B or hepatitis C, viruses that affect the liver
 - shingles
 - tuberculosis or have been in close contact with someone with tuberculosis
 - a fungal infection
 - any type of cancer, including skin cancer or a family history of skin cancer
 - diverticulitis (inflammation in parts of the large intestine) or ulcers in your stomach or intestines
 - liver or kidney problems, including kidney transplant surgery
 - high blood pressure
 - chest pain or any heart problems
 - lung disease or shortness of breath
 - high cholesterol
 - history of allergies or allergic reactions
 - bone-related conditions
 - any other medical conditions.
- you take any medicines for any other condition
- you plan to have surgery or a medical procedure
- you are a smoker or have been a smoker in the past

Your doctor will do blood tests before you start treatment with Tofacitinib Devatis and while you are taking it. Depending on the results of your blood tests your doctor may suspend or discontinue treatment or prescribe you additional medicines.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section “Side Effects”.

Serious infections

It is important to tell your doctor if you get symptoms of an infection.

Tofacitinib Devatis can lower the ability of your immune system to fight infections. Some people have serious infections while taking Tofacitinib Devatis, including tuberculosis and infections caused by bacteria, fungi or viruses that can spread in your body. In rare cases these infections can be life threatening.

Symptoms of an infection include fever, sweating or chills; muscle aches; cough, shortness of breath, weight loss; warm, red or painful skin or sores on your body; diarrhoea or stomach pain; burning when you urinate or urinating more often than normal, feeling very tired.

Symptoms of tuberculosis include persistent cough, coughing up blood, weight loss, fever and lack of energy.

Your doctor will check for signs and symptoms of tuberculosis before you start treatment. This will include a thorough medical history, a chest X-ray and other tests. Your doctor will also monitor you for signs of tuberculosis while you are being treated with Tofacitinib Devatis.

Tell your doctor if you have lived in or travelled to countries where there is an increased chance of getting tuberculosis or fungal infections.

Shingles (herpes zoster virus)

Tell your doctor if you have ever had shingles. Tofacitinib Devatis can reactivate the herpes zoster virus in people who carry this virus.

Serious heart-related problems

In a study in patients with rheumatoid arthritis who were 50 years of age and older with at least 1 additional heart disease (cardiovascular) risk factor, patients taking tofacitinib had an increased risk of non-fatal heart attacks compared to another type of medicine called tumour necrosis factor (TNF) inhibitors. Serious heart-related problems were more common in older patients and in patients who were current or past smokers.

Cancers

In a study in patients with rheumatoid arthritis who were 50 years of age and older with at least 1 additional heart disease (cardiovascular) risk factor, patients taking tofacitinib had an increased risk of getting cancers compared to another type of medicine called tumour necrosis factor (TNF) inhibitors. Cancers were more common in older patients and in patients who were current or past smokers.

Asian patients

Tell your doctor if you have Japanese or Korean ancestry. The risk of shingles may be higher in people with Japanese or Korean ancestry.

Hepatitis B virus (HBV) or hepatitis C virus (HCV)

Tell your doctor if you are a carrier of the hepatitis B virus (HBV) or hepatitis C virus (HCV), or if you have hepatitis B or C infection. If you have HBV or HCV in your blood, it may become active while you are taking Tofacitinib Devatis. This effect has been reported with medicines used to treat rheumatoid arthritis, including tofacitinib.

Vaccination

Make sure you are up to date with all vaccinations before starting Tofacitinib Devatis.

Tell your doctor if you have recently been vaccinated or are scheduled for any vaccines. Some vaccines should not be given while you are taking Tofacitinib Devatis. Check with your doctor before you receive any vaccines. Your doctor will decide whether you need to have herpes zoster vaccination.

Pregnancy and breastfeeding

Tell your doctor if you are pregnant or intend to become pregnant. Do not take Tofacitinib Devatis if you are pregnant or attempting to become pregnant. Your doctor can discuss with you the risks and benefits involved.

Use effective birth control during treatment with Tofacitinib Devatis and after the last dose, for as long as your doctor recommends, if you are a woman of childbearing age.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known if tofacitinib is found in breast milk. Do not breast-feed if you are taking Tofacitinib Devatis.

Use in children

- The safety and effectiveness of tofacitinib in children and adolescents have not been established.

Use in the elderly

- Patients over 65 years old have an increased chance of getting certain side effects including infections and blood clots.
- In a study in patients with rheumatoid arthritis who were 50 years of age and older with at least 1 additional heart disease (cardiovascular) risk factor, patients taking tofacitinib had an increased risk of getting certain side effects, including heart attacks and cancer. These side effects were more common in older patients.

If you have not told your doctor about any of the above, tell them before you start using Tofacitinib Devatis.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking Tofacitinib Devatis.

Some medicines may interfere with Tofacitinib Devatis and affect how it works.

You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you.

Tell your doctor or pharmacist if you are taking any of the following:

- antibiotics to treat bacterial infections such as rifampicin
- medicines to treat fungal infections, such as fluconazole and ketoconazole
- medicines to treat heart rhythm, angina and blood pressure
- medicines to suppress your immune system, such as azathioprine, tacrolimus, ciclosporin and mycophenolate
- any other medicines to treat rheumatoid arthritis.

These medicines may be affected by Tofacitinib Devatis, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Tofacitinib Devatis.

Tofacitinib Devatis must not be taken with some medicines to treat rheumatoid arthritis such as certolizumab or adalimumab, but can be taken with medicines such as methotrexate, leflunomide and sulfasalazine.

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Tofacitinib Devatis.

How to take Tofacitinib Devatis

How much to take

Your doctor will tell you how many tablets you need to take each day.

- The usual dose is one 5 mg tablet taken twice a day
- Your doctor may adjust the dose. This may depend on your medical conditions (e.g. liver or kidney problems), results of your blood tests and whether you are taking any other medicines.

When to take it

Take Tofacitinib Devatis tablets at about the same time each morning and evening. It will help you remember when to take it.

How to take it

- Swallow the tablets whole with a full glass of water.
- You can take Tofacitinib Devatis with or without food.

How long to take it

- Continue taking your medicine for as long as your doctor tells you.
- This medicine helps to control your condition but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose you missed.

While you are using Tofacitinib Devatis

Things you must do

- Keep all your appointments so that your progress can be checked.
- Keep your appointments for blood tests to make sure Tofacitinib Devatis is working and to check for any side effects.

- Wear sunscreen and a hat when outdoors and avoid getting sunburnt.
- Get regular skin checks.
- If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Tofacitinib Devatis.
- Remind any doctor or dentist you visit that you are taking Tofacitinib Devatis.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking Tofacitinib Devatis.
- Use effective birth control while taking Tofacitinib Devatis and after the last dose, for as long as your doctor recommends, if you are a woman of childbearing age.

Call your doctor straight away if you:

- have any signs and symptoms of an infection, during or after treatment, such as fever, sweating and chills, burning when you urinate, shortness of breath, cough, phlegm, wounds or warm, red or painful skin or sores on your body, feeling very tired.
Tofacitinib Devatis may 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.
- develop a persistent cough, blood in your phlegm or mucous, chest pain, fever, night sweats, weight loss, loss of appetite.
- have any signs and symptoms of a blood clot, such as sudden shortness of breath or difficulty breathing, chest pain, excessive sweating, rapid or irregular heartbeat, swelling of the leg or arm, leg pain or tenderness, or redness or discolouration in the leg or arm.
- notice any new spots on your skin, a spot that looks different, a sore that does not heal, a mole or freckle that has changed size, shape, colour or bleeds.
- become pregnant while taking Tofacitinib Devatis.

Things you must do

- Do not take Tofacitinib Devatis to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not stop taking your medicine, or change the dosage, without checking with your doctor.

Things to be careful of

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Tofacitinib Devatis affects you.

Drinking alcohol

No information is available.

In case of overdose

If you take too much (overdose)

You should immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too Tofacitinib Devatis.

Do this even if there are no signs of discomfort or poisoning.

You should do this even if there are no signs of discomfort or poisoning.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Tofacitinib Devatis.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Ask your doctor or pharmacist to answer any questions you may have.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Common side effects

Common side effects	What to do
Body as a whole: <ul style="list-style-type: none"> weight gain Gastrointestinal related: <ul style="list-style-type: none"> stomach pain, indigestion or heart burn nausea (feeling sick), vomiting, diarrhoea or constipation General disorders: <ul style="list-style-type: none"> swollen feet or hands Infection related: <ul style="list-style-type: none"> a cold, sore throat, runny or blocked nose, pain in your sinus cough flu cold sore blisters Muscle or Bone related: <ul style="list-style-type: none"> joint or back pain Nervous system: <ul style="list-style-type: none"> headaches, dizziness Skin related: <ul style="list-style-type: none"> skin, redness or itching 	Speak to your doctor if you have any of these common side effects and they worry you.

Serious side effects

Serious side effects	What to do
Signs of a possible serious infection: <ul style="list-style-type: none"> fever, sweating and chills burning when you urinate shortness of breath, cough, phlegm wounds or warm, red or painful skin or sores on your body feeling very tired Lung or heart related: <ul style="list-style-type: none"> persistent cough, coughing up blood, weight loss, lack of energy breathlessness during exercise or a dry cough Liver related: <ul style="list-style-type: none"> fatigue, yellowing of the skin or eyes, dark urine, loss of appetite Gastrointestinal related:	Call your doctor straight away if you notice any of these serious side effects.

<ul style="list-style-type: none"> • a stomach ache or pain that won't go away, a change in bowel habits <p>Blood disorders:</p> <ul style="list-style-type: none"> • tiredness, headaches, shortness of breath when exercising, dizziness, and looking pale <p>Skin related:</p> <ul style="list-style-type: none"> • painful skin rash with blisters • a change in the appearance of a freckle, mole or spot, a sore that doesn't heal 	
<p>Signs of an allergic reaction:</p> <ul style="list-style-type: none"> • shortness of breath, wheezing or difficulty breathing • swelling of the face, lips, tongue or other parts of the body • severe rash, itching or hives <p>Signs of a blood clot:</p> <ul style="list-style-type: none"> • sudden shortness of breath or difficulty breathing, chest pain, excessive sweating, rapid or irregular heartbeat • swelling of the leg or arm, leg pain or tenderness, or redness or discolouration in the leg or arm <p>Blood disorders:</p> <ul style="list-style-type: none"> • persistent fever, bruising, bleeding, paleness • swelling of the glands in your neck, armpits or groin <p>Signs of meningitis:</p> <ul style="list-style-type: none"> • fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to bright light <p>Signs of sepsis:</p> <ul style="list-style-type: none"> • fever, chills, uncontrollable shaking, rapid breathing and heart rate, headache, confusion or anxiety, drowsiness, reduced urine <p>Signs of heart attack:</p> <ul style="list-style-type: none"> • chest pain • pressure or tightness in the chest and arms that may spread to the jaw, neck or back • dizziness, nausea or vomiting 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.</p>

If you are over 65 years of age or have diabetes, you have an increased chance of getting certain side effects including infections. This may also be the case if you have chronic lung disease.

Asian patients may have an increased risk of getting certain side effects such as shingles or lung problems.

People with rheumatoid arthritis or problems with their immune system may be at increased risk of cancer, including lymphoma (symptoms include swelling of the glands in the neck, armpit or groin) and lung cancer.

As with some other treatments for rheumatoid arthritis, Tofacitinib Devatis may increase the risk of skin cancer.

Some side effects (for example, changes in cholesterol level or blood pressure) can only be found when your doctor does tests from time to time to check your progress.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

After using Tofacitinib Devatis

Storage

- Keep your tablets in the pack until it is time to take them.
- Store Tofacitinib Devatis below 30°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Do not use this medicine after the expiry date.

Keep it where young children cannot reach it.

Disposal

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Product description

What it looks like

Tofacitinib Devatis 5 mg tablets are white, biconvex, round (8.0 mm diameter) film coated tablet. Tofacitinib Devatis is available in blister packs containing 14 or 56 film coated tablets and HPDE bottles with a child-resistant closure containing of 60 film coated tablets.

Not all pack sizes may be marketed.

Ingredients

Active ingredient

Each tablet contains 8.08 mg of tofacitinib citrate equivalent to 5 mg of tofacitinib.

Inactive ingredients:

Microcrystalline cellulose
Lactose monohydrate
Croscarmellose sodium
Magnesium stearate

Tablet coating

Hypromellose
Titanium dioxide

Lactose monohydrate
Polyethylene Glycol / Macrogol
Triacetin

Do not take this medicine if you are allergic to any of these ingredients.

Sponsor details

Tofacitinib Devatis is supplied in New Zealand by:

Devatis Limited
Findex, 173 Spey Street, Invercargill 9810,
New Zealand
Toll Free Number: 0800 887750
www.devatis.nz

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