

Patient Education - Tofacitinib 4% Topical Gel

Hillcrest Pharmacy 781 E FT Union Blvd Midvale, UT 84047 – Direct 385-900-1400, Toll Free 1-855-499-2556

Patient Education Insert - Apply medication to affected area as prescribed

This medication was compounded by a pharmacy per prescriber request. For external use only. Wash hands before and after use unless the medication is for your hands. Store at room temperature (68 to 77 degrees Fahrenheit). Keep away from children and pets. Do not flush unused medications or pour down a sink or drain. Do not swallow and avoid contact with eyes. Do not use more than your medical provider has instructed you to use. Do not use more often or for longer than you were instructed. Doing any of these may increase the chance of side effects.

The “Do not use after” date printed on the prescription label is generated using State & Federal compounding laws. Some preparations are made 1-3 days before the prescription is issued, in anticipation of expected demand. If you have any questions or concerns regarding this, please call and speak to one of our pharmacists.

Do not use if an allergic reaction occurs due to any of the listed active ingredients on the prescription label. Signs of an allergic reaction may include rash hives itching shortness of breath wheezing cough swelling of face, lips, tongue or throat or any other signs.

Contact your medical provider or pharmacy if you have concerns about listed side effects or if you experience unexpected irritation. Notify your medical provider of any medical updates and of all drug changes including over-the-counter and herbal medications.

If you miss an application, apply as soon as you remember. If it is close to the next application, skip the missed application. Do not double applications.

We want to offer you the best service possible. In the event you have a concern or complaint please call the pharmacy at 385-900-1400.

MedWatch: The FDA Safety Information and Adverse Event Reporting Program - Website address: <https://www.fda.gov/Safety/MedWatch/default.htm> - Toll free number: 1-888-463-6332

Your medication contains the following active ingredients. Please review the following:

Tofacitinib is used to treat moderate to severe rheumatoid arthritis or active psoriatic arthritis in adults who have tried other medications without successful treatment of symptoms. Tofacitinib is sometimes given in combination with or other arthritis medicines. Tofacitinib may also be used for purposes not listed in this medication guide.

You should not use tofacitinib if you have a serious infection. Before you start treatment, your doctor may perform tests to make sure you do not have an infection.

Tofacitinib affects your immune system. You may get infections more easily, even serious or fatal infections. Call your doctor if you have a fever, chills, aches, tiredness, cough, trouble breathing, skin sores, diarrhea, weight loss, or burning when you urinate.

If you've ever had hepatitis B or C, using tofacitinib can cause this virus to become active or get worse. Tell your doctor if you don't feel well and you have right-sided upper stomach pain, vomiting, loss of appetite, or yellowing of your skin or eyes.

Tell your doctor if you have ever had: liver disease (especially hepatitis B or C) heart problems (especially if you are 50 or older) lung disease a blood clot a chronic infection HIV, or a weak immune system a stomach or intestinal problem such as diverticulitis or an ulcer kidney disease (or if you are on dialysis) diabetes or if you are scheduled to receive any vaccine.

Taking tofacitinib at too high a dose (usually oral dosing) may increase the risk of death in people with rheumatoid arthritis who are 50 and older and have at least 1 risk for heart disease. This includes high blood pressure, high cholesterol, diabetes, smoking, being overweight, or having a family history of heart disease. Talk to your doctor about your specific risk, and take only your recommended dose.

Tell your doctor if you have ever had tuberculosis or if anyone in your household has tuberculosis. Also tell your doctor if you have recently traveled. Tuberculosis and some fungal infections are more common in certain parts of the world, and you may have been exposed during travel.

Using tofacitinib may increase your risk of developing certain cancers, such as lymphoma or skin cancer. Ask your doctor about this risk.

It's not known if tofacitinib will harm an unborn baby. Tell your doctor if you are pregnant/plan to become pregnant. This may affect your ability to have children during treatment and in the future. Do not breastfeed while you are using this medicine, and for at least 18 hours after your last dose (36 hours if you take extended-release tablets). If you use a breast pump during this time, do not feed the milk to your baby.

Do not receive a "live" vaccine while using tofacitinib, or you could develop a serious infection. Live vaccines include measles, mumps, rubella (MMR), polio, rotavirus, typhoid, yellow fever, varicella (chickenpox), and zoster (shingles).

Get emergency medical help if you have signs of an allergic reaction: hives difficult breathing swelling of your face, lips, tongue, or throat.

Some people taking high doses of tofacitinib have developed serious or fatal blood clots. Stop taking tofacitinib and seek emergency medical attention if you have: sudden shortness of breath pain while breathing cough with pink or red mucus pain in your chest or back clammy or blue-colored skin, heavy sweating or pain, swelling, or redness in an arm or a leg.

You may get infections more easily, even serious or fatal infections. Call your doctor right away if you have signs of infection such as: fever, chills, sweating, tiredness, muscle pain feeling short of breath skin sores with warmth, redness, or swelling increased urination, pain or burning when you urinate mouth sores, stomach pain, diarrhea or signs of tuberculosis: fever, cough, night sweats, loss of appetite, weight loss, and feeling very tired.

Also call your doctor at once if you have: low red blood cells (anemia) pale skin, unusual tiredness, feeling light-headed or short of breath, cold hands and feet signs of hepatitis loss of appetite, vomiting, stomach pain (upper right side), dark urine, clay-colored stools, jaundice (yellowing of the skin or eyes) shingles burning pain, numbness, tingling, itching, skin rash or blisters or signs of perforation (a hole or tear) in your stomach or intestines fever, ongoing stomach pain, change in bowel habits.

Common side effects may include: skin rash, shingles increased blood pressure abnormal blood tests headache diarrhea or cold symptoms such as stuffy nose, sneezing, sore throat.

This is not a complete list of side effects and others may occur.