Jakenz

Tofacitinib **5mg, 10mg**

PATIENT ALERT CARD

This card is for patients who have been prescribed Jakenz (tofacitinib)

This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA

Version: 1.0
Date: October 2023

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- This card contains important safety information about Jakenz . If you do not understand this information, please ask your doctor/pharmacist to explain it to you
- Keep this card with you and show it to any doctor or pharmacist involved in your care. If you stop taking Jakenz , keep this card with you for at least 2 months after taking the last dose of Jakenz

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- See the Jakenz patient information leaflet for more information. You should use Jakenz according to the patient information leaflet

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Tell your doctor or your pharmacist about ALL the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements.

Some medicines should not be taken with Jakenz as they could alter the level of Jakenz in your body and your dose may require adjustment. You should tell your doctor if you are using medicines that contain the following active substances:

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- antibiotics such as rifampicin, used to treat bacterial infections
- fluconazole and ketoconazole used to treat fungal infections

Jakenz is not recommended for use with biologic disease-modifying antirheumatic drugs (DMARDs) for rheumatoid arthritis or psoriatic arthritis, biologics for ulcerative colitis, or with certain other medicines that depress your immune system (e.g., azathioprine,

mercaptopurine, tacrolimus or ciclosporin). Taking Jakenz with these medicines may increase your risk of immunosuppression and infection.

Treatment with Jakenz may increase the risk of infections, malignancies (including lung cancer, lymphoma, and non melanoma skin cancer).

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

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During treatment with Jakenz

Tell your doctor ***immediately*** 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 Jakenz , as these may be signs of a clot in the lungs or veins

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- Develop symptoms of an infection, such as fever, persistent cough, weight loss, or excessive tiredness
- Develop any symptoms of herpes zoster, such as painful skin rash or blisters
- Have been in close contact with a person with tuberculosis

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- Develop severe chest pain or tightness (that may spread to arms, jaw, neck and back), shortness of breath, cold sweat, light headedness or sudden dizziness, as these may be signs of a heart attack
- Develop any swelling of lymph nodes in your neck, armpits, or groin; constantly feeling tired; fever; night sweats; persistent or worsening cough; difficulty breathing; hoarseness or wheezing; or unexplained weight loss

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- Notice any new growth on the skin or any changes in existing moles or spots
- Develop symptoms of lung disease, such as shortness of breath
- Develop abdominal signs and symptoms such as stomach pain, abdominal pain, blood in your stool, or any change in your bowel habits with fever

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- Develop yellow skin, nausea or vomiting
- Are due to receive any vaccine. You should not receive certain types of vaccines while taking Jakenz
- Become pregnant or plan on becoming pregnant. Jakenz must not be used during pregnancy. Women of childbearing potential should be advised to use effective contraception during treatment with Jakenz and for at least 4 weeks after the last dose

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- Women must not breast-feed while being treated with Jakenz

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Other Information (please complete)

Patient's Name:

Doctor's Name:

Doctor's Phone:

Doctor's Fax:

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You can help by reporting any side effects you may get. If you get any side effects talk to your doctor, pharmacist or nurse.Please report suspected adverse drug reactions (ADRs) National Pharmacovigilance Centre (NPC)- Saudi Food and Drug Authority (SFDA) via:

Website: https://ade.sfda.gov.sa,
Email: npc.drug@sfda.gov.sa,
Call center: 19999

Also, you can report to Sudair Pharma Company via:

Phone: +966-920001432 Ext. 107
Email: Pharmacovigilance@SudairPharma.com

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