PATIENT ALERT CARD

TOFACI (TOFACITINIB CITRATE) 5MG& 10 MG TABLETS

This document is approved by the Executive Directorate of Pharmacovigilance at SFDA

Version 01

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Amarox

TOFACI Patient Safety Card

- This card contains important safety information that you need to be aware of before you start talking TOFACI and during your treatment with Afatinib. 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.
- See the TOFACI package leaflet for more information.

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

TOFACI is not recommended for use with biologic DMARDs for rheumatoid arthritis or with certain other medicines that depress your immune system (e.g., azathioprine, tacrolimus, cyclosporine or mycophenolate). Taking TOFACI with these medicines may increase your risk of infection.

During treatment with TOFACI

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 TOFACI, as these may be signs of a clot in the lungs or veins.
- Develop symptoms of an infection, such as fever, persistent cough, weight loss, or excessive tiredness. TOFACI may increase your risk of getting infections, which can become serious if not treated. You may be at higher risk for infections if you are 65 years of age or older, have diabetes, chronic lung disease, or taking corticosteroids. Your TOFACI treatment may be stopped by your doctor.
- Develop symptoms of lung disease, such as shortness of breath.
- 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.
- Notice any new growth on the skin or any changes in existing moles or spots.

Seek **immediate** medical attention and stop taking TOFACI

Until you discuss with your doctor if :

- Experience possible symptoms of allergic reactions such as chest tightness, wheezing, severe dizziness or light-headedness, swelling of the lips, tongue or throat, itching or skin rash when taking TOFACI, or soon after taking TOFACI.

Other Information (Please complete)

Patient's Name:

Doctor's Name:

Doctor's Phone:

Hospital Name:

Hospital Phone:

TOFACI Treatment start date:

If you stop taking TOFACI keep this card with you for at least 2 months after taking the last dose of TOFACI.

Reporting Side Effects:

To report any suspected adverse reactions to, kindly contact:

National Pharmacovigilance Centre at Saudi Food and Drug Authority (SFDA):

SFDA call centre: 19999

E-mail: npc.drug@sfda.gov.sa

Website: https://ade.sfda.gov.sa

Marketing Authorization Holder Contact Information:
Saudi Amarox Industrial Company
Razan almalki
Pharmacovigilance Specialist

Al JamiyahStreet –Al Malaz–Riyadh Code 12629, Saudi Arabia.

Phone: +966 11 226 8850

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• Develop any symptoms of herpes zoster, such as painful skin rash or blisters. • Have been in close contact with a person with tuberculosis. • 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. • Develop abdominal signs and symptoms such as stomach pain, abdominal pain, blood in your stool, or any change in your bowel habits with fever. • Develop yellow skin, nausea or vomiting. • Are due to receive any vaccine. You should not receive certain types of vaccines while taking TOFACI. • Become pregnant or plan on becoming pregnant. TOFACI should not be used during pregnancy unless clearly necessary. Women of childbearing potential should be advised to use effective contraception during treatment with TOFACI and for at least 4 weeks after the last dose. Women should not breast-feed while being treated with TOFACI.	