Tyenne Tocilizumab (SC and IV)
Patient Alert Card

This Patient Alert Card contains **important safety information** that you need to be aware of before and during treatment with Tyenne.

This patient alert card must be read together with the Tyenne Patient Brochure provided by your physician and the Tyenne Package Leaflet that comes with your medication, as it contains important information about Tyenne, including Instructions for Use.

Show this card to ANY healthcare professional involved in your care.

Keep this card with you for at least 3 months after your last Tyenne dose, since side effects could occur for some time after your last dose of Tyenne. If you experience any untoward effects and have been treated with Tyenne in the past, contact the healthcare professional for advice.

This document is approved by The Executive Directorate of Pharmacovigilance at Saudi Food and Drug Authority (SFDA) | Version 1.0 Date of last revision: 8.2023

Dates of Tyenne Treatment:

Most recent: _____

Route of administration:

Under the skin (subcutaneous, SC) injection	**SC**
Into the vien (intravenous, IV) infusion	**IV**

Next scheduled administration: _____

Please make sure you also bring a list of all your other medicines with you at any visit to a healthcare professional.

Contact Information

Patient's Name

Doctor's Name

Doctor's Phone

Infections

You should not receive Tyenne if you have an active serious infection. In addition, some previous infections may reappear with use of Tyenne.

- Talk to your healthcare professional about any vaccinations you may need before starting treatment with Tyenne.
- You should have been screened and found to have no active tuberculosis prior to treatment with Tyenne.
- Tell your doctor immediately if you experience signs or symptoms of infection, such as persistent cough, wasting/weight loss or low-grade fever, during or after treatment with Tyenne. This may be suggestive of a tuberculosis infection.
- Younger children may be less able to communicate their symptoms; therefore parents/guardians/caregivers of younger children should contact their healthcare professional immediately if their child is unwell for no apparent reason.
- Seek guidance from your healthcare professional about whether you should delay the next treatment if you have an infection of any kind (even a head cold) at the time of your scheduled treatment.

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Allergic Reactions

Most allergic reactions occur during the injection/infusion, or within 24 houses of Tyenne administration, although allergic reactions can occur at ant time.

Serious allergic reactions, including anaphylaxis, have been reported in association with Tyenne. Such reactions may be more severe, and potentially fatal, in patients who have experienced allergic reactions during previous treatment with Tyenne.

IV infusion (in the clinic)	SC injections (in the clinic or at home)
During the infusion, the doctor or nurse will be monitoring you closely for any signs of an allergic reaction.	The doctor will assess your suitability to use Tyenne SC injections at home. If you experience any symptoms suggestive of an allergic reaction, you should not take the next dose until you have informed your doctor AND the doctor has told you that you should take the next dose.

You should seek immediate medical attention and **Tyenne should be stopped immediately** and permanently discontinued if a severe hypersensitivity reaction (also known as anaphylaxis) occurs. Symptoms include the following:

- Rash, itching or hives
- Shortness of breath or trouble breathing
- Swelling of the lips, tongue or face
- Chest pain or chest tightness
- Feeling dizzy or faint
- Severe stomach pain or vomiting
- Very low blood pressure

Complications of Diverticulitis

Patients using Tyenne may develop complications of diverticulitis, which can become serious if not treated.

- Seek immediate medical attention if you develop stomach pain or colic with a change in bowel habits, or notice blood in your stool.
- Inform your doctor if you have or have had intestinal ulceration or diverticulitis (inflammation in parts of the large intestine).

Hepatotoxicity

If you have liver disease, tell your doctor before you receive Tyenne. Before you use Tyenne, your doctor may do a blood test to measure your liver function.

Liver Problems

Increases in a specific set of blood laboratory tests, called liver enzymes, have been seen commonly in the blood of patients treated with Tyenne. You will be monitored closely for changes in liver enzymes in the blood during treatment with Tyenne and appropriate action taken by your doctor.

On rare occasions, patients have experienced serious life-threatening liver problems, some of which have required liver transplant. Rare side effects, which may affect up to 1 in every 1,000 users, include inflammation of the liver (hepatitis) and jaundice. Very rare side effects, which may affect up to 1 in every 10,000 users, include liver failure.

Tell your doctor immediately if you notice a yellowing of the skin and eyes, have dark brown coloured urine, pain or swelling in the upper right side of the stomach area or you feel very tired and confused. You might not have any symptoms, in which case this increase in liver enzymes will be picked up during blood tests.

Call for Reporting

Talk to the doctor, nurse or pharmacist immediately, if you have any questions or experience any side effects. This includes any possible side effects not listed in this document.

For full information on all possible side effects, please see the Tyenne Package Leaflet.

Please report any suspected adverse events associated with the use of Tyenne (Tocilizumab) through:

Boston Oncology Arabia Limited
King Abdelaziz Street, 11562, Riyadh, Saudi Arabia
Phone: 011 245 5311 | Mobile: +966 547 643 672
E-mail: pv@bostononcology.com

The National Pharmacovigilance Centre (NPC)
SFDA Call Centre: 19999 | E-mail: npc.drug@sfda.gov.sa
Website: https://ade.sfda.gov.sa/

By reporting side effects, you can help provide more information on the safety of this medicine.

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