FOR USE IN IRELAND

Tyenne®
tocilizumab
(SC and IV)

# Patient Alert Card

Show this card to ANY healthcare professional involved in your/your child's care.

## Patient Alert Card:

Please read this card along with the Package Leaflet supplied with this medicine or also available on www.medicines.ie before taking this medicine.

Show this card to ANY healthcare professional involved in your/your child's care.

This Patient Alert Card contains important safety information that you need to be aware of before and during treatment with Tyenne. For use with paediatric and adult patients.

This Patient Alert Card must be read together with the Tyenne Patient Brochure (provided by your doctor) and the Tyenne Package Leaflet that comes with your medication (and is also available on www.medicines.ie) as it contains important information about Tyenne including Instructions for Use.

Note: this card is for use by Tyenne patients (or their parents/guardians if the patient is a child).

This patient alert card contains important safety information that patients or parents/guardians of patients need to be aware of before, during and after treatment with Tyenne. Tyenne treatment may be administered as an intravenous (IV) infusion or subcutaneous (SC) injection.

### General

As a Rheumatoid Arthritis (RA), polyarticular Juvenile Idiopathic Arthritis (pJIA), or systemic Juvenile Idiopathic Arthritis (sJIA) patient, your treatment may be administered as an IV infusion or SC injection

As a Giant Cell Arteritis (GCA) patient, your treatment will be by SC injection only. As a COVID-19 patient, your treatment will be IV infusion only.

### Infections

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

- Infections can become serious if not treated so tell your/your child's doctor immediately if signs/symptoms of infection develop such as:
  - Fever and chills
  - Persistent cough
  - Weight loss
  - Throat pain or soreness
  - Wheezing
  - Red or swollen skin or mouth blisters, skin tears or wounds
  - Severe weakness or tiredness
  - Stomach ache
- Before starting treatment with Tyenne, tell the doctor if you/your child have recently been vaccinated and talk to the doctor about any vaccinations that you/your child may need.
- Patients should be up-to-date with all their vaccinations before they start treatment with Tyenne
- Seek immediate medical advice if you/your child develop any signs/symptoms suggestive of a tuberculosis infection (such as persistent cough, wasting/weight loss, listlessness, mild fever) during or after treatment with Tyenne. You/your child should have been screened and found to have no active tuberculosis prior to treatment with Tyenne
- Younger children may be less able to communicate their symptoms; therefore parents/guardians/ caregivers of younger children should contact the doctor immediately if their child is unwell for no apparent reason
- Seek guidance from your/your child's doctor about whether the next treatment should be delayed if you/your child have aninfection of any kind (even a head cold) at the time of your scheduled treatment

### Complications of diverticulitis

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

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

## Hepatotoxicity

**If you/your child has liver disease, tell your doctor**. Before you/your child uses Tyenne, your doctor may do a blood test to measure your/your child's liver function. Increases in a specific set of blood laboratory tests called liver enzymes have been seen commonly in the blood of patients with Tyenne.

You/your child will be monitored closely for changes in liver enzymes in the blood during treatment with Tyenne and appropriate action taken by your doctor.

Inflammation of the liver (hepatitis) and jaundice have been reported rarely with Tyenne (rare side effects may affect up to 1 in every 1,000 users). Serious cases of life-threatening liver problems, some of which resulted in liver transplantation, have been reported very rarely with Tyenne (very rare side effects may affect up to 1 in every 10,000 users).

- **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/your child might not have any symptoms in which case any increase in liver enzymes will be detected by blood tests.

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

## Dates of Tyenne treatment:*

| | | |
|---|---|---|
| **Start:** | | |
| **Most recent:** | | |
| **Route of administration:** | IV | SC |
| **Doctor's name:** | | |
| **Patient's/Parent's/ Guardian's name:** | | |
| **Doctor's phone number:** | | |

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

## Further Information

Talk to your doctor, nurse or pharmacist if you have any questions or concerns.

Reporting of side effects
For full information on all possible side effects please see the Tyenne Package Leaflet, which can be found at the EMA website (www.ema.europa.eu) or www.medicines.ie.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the Package Leaflet.You can also report side effects directly in Ireland to: HPRA Pharmacovigilance Website: www.hpra.ie

You should also report side effects to Fresenius Kabi by emailing pharmacovigilance.gb@fresenius-kabi.com or calling +44 1928 533 575.

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

**Notes** (comments or questions for your doctor)

## Contact Medical Information

pharmacovigilance.gb@fresenius-kabi.com
Tel: +44 1928 533 575.

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Date of Preparation: October 2023
IE-TYE-2300042