Tuyory® (tocilizumab)

- 20mg/ml concentrate for solution for infusion
- 162 mg solution for injection in pre-filled syringe
- 162 mg solution for injection in pre-filled pen

PATIENT CARD

This card is for both paediatric and adult patients. Use accordingly.

This card is provided to further minimise the risks associated with the use of Tuyory and to guide patients when to seek medical advice

This educational material is provided by Gedeon Richter UK Ltd and is mandatory as a condition of the Marketing Authorisation to further minimise important selected risks.

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GEDEON RICHTER

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

- Show this card to ANY healthcare professional involved in your care
- Read the Patient Information Leaflet that comes with your medicine

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

Tuyory may make an existing infection worse or increase the chance of getting a new infection. You should not receive Tuyory if you have an active serious infection. In addition, some previous infections may reappear with use of Tuyory.

- Seek medical advice if any signs/ symptoms (such as persistent cough, wasting/ weight loss, low-grade fever) suggestive of a tuberculosis (TB) infection occurring during or after treatment with Tuyory. You should have been screened and found to have no active TB prior to treatment with Tuyory
- Tell your doctor immediately if you experience signs or symptoms of an infection. Some infections might become very serious and may require immediate treatment and hospitalisation. Seek immediate medical attention if you experience any signs symptoms of an infection, including:
  - 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 pain
- Talk to your healthcare professional about any vaccinations you may need before you start treatment with Tuyory
- Seek guidance from your healthcare professional about whether you should delay your next treatment if you have an infection of any kind (even a head cold) at the time of your scheduled treatment
- Younger children with pJIA/sJIA may be less able to communicate their symptoms therefore parents/guardians of pJIA or sJIA patients should contact their healthcare professional immediately if their child is unwell for no apparent reason

Complications of diverticulitis

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

- **Seek immediate medical attention** if you develop fever and or persistent stomach pain or colic with change in bowel habits or notice blood in your stool and inform your doctor that you are taking Tuyory
- Inform your doctor if you have or have had intestinal ulceration or diverticulitis (inflammation in parts of your large intestine)

Hepatotoxicity

Tuyory treatment can often cause an increase in a specific set of blood laboratory tests called 'liver enzyme' tests which are used to measure the function of your liver. Changes in these liver enzyme blood tests will be monitored regularly while you are receiving Tuyory.

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 patients receiving Tuyory, include inflammation of the liver (hepatitis) and jaundice (yellowing of the skin).

Very rarely (affecting 1 in every 10,000 patients receiving Tuyory) patients can experience 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
- Tell your doctor if you have liver disease before you receive Tuyory

CRP (C-reactive protein) levels

Tuyory suppresses the acute-phase response (inflammatory response), i.e., it normalizes CRP and ESR levels. Therefore, particular attention is needed for the timely diagnosis of a serious infection in patients treated with biologics. Signs and symptoms of a serious infection may be attenuated by suppression of the acute-phase response.

Factors to consider:

- Tuyory normalizes CRP levels rapidly in most patients, within two weeks, indicating reduced systemic inflammation.
  Therefore, the CRP level may not be a reliable indicator of infection in patients undergoing Tuyory therapy
- The effects of Tuyory on CRP, on neutrophils (which may be reduced), and on signs and symptoms of infection (e.g., suppression of fever) must be considered when a patient is being screened for potential infection

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

CALL FOR SIDE EFFECTS REPORTING

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 via the Yellow Card Scheme at: **https://yellowcard.mhra.gov.uk/**. By reporting side effects, you can help provide more information on the safety of this medicine.

Dates of Tuyory treatment:*

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

Indication:

Start of treatment:

Last treatment:

Dosage:

Route of administration: ❑ **IV** / ❑ **SC**

Patient's/Parent's/Guardian's name:

Doctor's name:

Doctor's phone number: