

Tyenne Tocilizumab

Patient Brochure

Important Safety Information for Patients

This Patient Brochure contains Instructions for Use, and important safety information that patients and their caregivers need to be aware of before and during treatment with Tyenne.

Please carefully read this Patient Brochure, along with the Tyenne Patient Alert Card provided by your physician and the Tyenne Package Leaflet that comes with your medication, and save them as references.

The information that you receive in these documents complements the information that you will receive from your physician, nurse, or pharmacist.

If any of the information is not clear to you, ask your physician, nurse, or pharmacist for clarification.

How is Tyenne given?

Tyenne is administered either as an intravenous (into a vein) (IV) infusion with a needle or subcutaneous (under the skin) (SC) injection using a pre-filled syringe or pen.

Intravenous Formulation

Tyenne IV is used to treat:

- **Adults with moderate to severe active rheumatoid arthritis (RA)**, an autoimmune disease, if previous therapies did not work well enough. Tyenne is usually given in combination with methotrexate. However, Tyenne can be given alone if your doctor determines that methotrexate is inappropriate. Tyenne can also be used to treat adults who have not had previous methotrexate treatment if they have severe, active and progressive rheumatoid arthritis.
- **Children aged 2 years and over who have active systemic juvenile idiopathic arthritis (sJIA)**, an inflammatory disease that causes pain and swelling in one or more joints as well as fever and rash. Tyenne is used to improve the symptoms of sJIA and can be given in combination with methotrexate or alone.
- **Children aged 2 years and over with active polyarticular juvenile idiopathic arthritis (pJIA)**, an inflammatory disease that causes pain and swelling in one or more joints. Tyenne is used to improve the symptoms of pJIA and can be given in combination with methotrexate or alone.

Subcutaneous Formulation (using a pre-filled syringe)

Tyenne SC PFS is used to treat:

- **Adults with moderate to severe active rheumatoid arthritis (RA)**, an autoimmune disease, if previous therapies did not work well enough.
- **Adults with severe, active and progressive rheumatoid arthritis (RA)**, who have not had previous treatment with methotrexate. Tyenne helps to reduce RA symptoms such as pain and swelling in your joints, and can also improve your performance of daily tasks. Tyenne has been shown to slow the damage to the cartilage and bone of the joints caused by the disease, and to improve your ability to do normal daily activities. Tyenne is usually given in combination with another medicine for RA called methotrexate. However, Tyenne can be given alone if your doctor determines that methotrexate is inappropriate.

- **Children and adolescents, aged 2 year and over, with active systemic juvenile idiopathic arthritis (sJIA)**, an inflammatory disease that causes pain and swelling in one or more joints as well as fever and rash. Tyenne is used to improve the symptoms of sJIA. It can be given in combination with methotrexate or alone.
- **Children and adolescents, aged 2 years and over, with active polyarticular juvenile idiopathic arthritis (pJIA)**, an inflammatory disease that causes pain and swelling in one or more joints. Tyenne is used to improve the symptoms of pJIA. It can be given in combination with methotrexate or alone.

Subcutaneous Formulation (using a pre-filled pen only)

Tyenne SC PFP is used to treat:

- **Children and adolescents, aged 12 years and over, with active systemic juvenile idiopathic arthritis (sJIA)**, an inflammatory disease that causes pain and swelling in one or more joints as well as fever and rash. Tyenne is used to improve the symptoms of sJIA. It can be given in combination with methotrexate or alone.
- **Children and adolescents, aged 12 years and over, with active polyarticular juvenile idiopathic arthritis (pJIA)**, an inflammatory disease that causes pain and swelling in one or more joints. Tyenne is used to improve the symptoms of pJIA. It can be given in combination with methotrexate or alone.

Before starting treatment with Tyenne (tocilizumab)

Before starting Tyenne, tell the doctor or nurse if you:

- Have signs of an infection (such as a fever, cough or headache), have a skin infection with open sores (chicken pox or shingles), are being treated for an infection, or get frequent infections
- Have diabetes or other conditions that increase the chance for infections
- Have tuberculosis (TB) or have been in close contact with someone who has had TB. Your doctor should test you for TB before starting Tyenne.
- Have or have had intestinal ulcers or diverticulitis
- Have or have had liver disease or viral hepatitis
- Have recently had a vaccination (immunisation), such as that for MMR, or are scheduled to have one. You should be brought up to date with all immunisations before starting Tyenne. Certain types of vaccines should not be administered while on Tyenne.

- Have cancer. Discuss with your prescriber if you should receive Tyenne.
- Have heart or circulatory disease, such as high blood pressure or high cholesterol
- Have had any allergic reactions to previous medications, including Tyenne
- Have had or now have impaired lung function (e.g. interstitial lung disease, where inflammation and scarring in the lungs make it difficult to get enough oxygen)

In addition, for patients with sJIA, also tell the doctor or nurse if you:

- Have a history of macrophage activation syndrome
- Are taking any other medications to treat sJIA. This includes oral medications, such as NSAIDs (e.g. ibuprofen), corticosteroids, methotrexate (MTX) and biologic drugs.

During treatment with Tyenne (tocilizumab)

What tests will be done when receiving treatment with Tyenne?

At each visit to see your doctor or nurse, they may test your blood to help guide your treatment. Here are some things they may look at:

- **Neutrophils.** Having enough neutrophils is important to help our bodies fight infections. Tyenne works on the immune system and can cause the number of neutrophils, a form of white blood cells, to drop. For this reason, your doctor may test to make sure you have enough neutrophils and monitor for signs and symptoms of infection.
- **Platelets.** Platelets are small blood components that help stop bleeding by forming clots. Some people taking Tyenne had a drop in the number of platelets in their blood. In clinical trials, the drop in platelets was not associated with any serious bleeding.
- **Liver enzymes.** Liver enzymes are proteins produced by your liver which may be released into your blood, sometimes indicating liver damage or disease. Some people who have taken Tyenne have had a rise in liver enzymes, which could be a sign of liver damage. Rises in liver enzymes were seen more often when medications that could be harmful to the liver were used with Tyenne. If you have a rise in liver enzymes, your doctor should take care of this right away. Your doctor may decide to change your dose of Tyenne, or of other medications, or potentially stop treatment with Tyenne altogether.
- **Cholesterol.** Some people who have taken Tyenne have had a rise in blood cholesterol, which is a type of lipid (fat). If you have an increase in cholesterol, your doctor may prescribe a cholesterol-lowering medication.

Can patients have vaccinations during treatment with Tyenne?

Tyenne is a medication that affects the immune system and may lower the body's ability to fight infection. Immunisation with live or live-attenuated vaccines (which contain very small amounts of the actual germ or weakened germs, such as the flu vaccine or the measles, mumps, rubella (MMR) vaccine) should not be given during treatment with Tyenne.

What are the potential serious side effects of Tyenne?

Infections

Tyenne is a medication that affects your immune system. Your immune system is important because it helps you fight infections. Your ability to fight infections may be lowered with Tyenne. Some infections may become serious while on Tyenne. Serious infections may require treatment and hospitalization and in some cases may lead to death.

Seek immediate medical attention if you develop signs/symptoms of infection 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

Allergic Reactions

Most allergic reactions occur during injection or within 24 hours of Tyenne administration, although allergic reactions can occur at any 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. Fatal anaphylaxis has been reported during treatment with Tyenne.

If an anaphylactic reaction or other serious allergic reaction occurs, administration of Tyenne should be stopped immediately, appropriate medical treatment initiated, and Tyenne should be permanently discontinued.

Seek immediate medical attention if you notice any of the following signs or symptoms of allergic reactions:

- 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

If you have experienced any allergic reaction symptoms after receiving Tyenne or if you are administering Tyenne at home and you experience any symptoms suggestive of an allergic reaction:

- **Do not take the next dose until you have informed your doctor AND your doctor has told you to take the next dose**
- **Always tell the doctor before your next dose if you experience any allergic reaction symptoms after you receive Tyenne**

Abdominal Pain

Patients taking Tyenne have on rare occasions experienced serious side effects in their stomach and intestines. Symptoms may include fever and persistent abdominal pain with changes in bowel habits. **Seek immediate medical attention** if you develop stomach pain or colic or notice blood in your stool.

Malignancies

Medicinal products which act on the immune system, like Tyenne, may increase the risk of malignancy.

Hepatotoxicity

If you have liver disease, tell your doctor. 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, are 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.

Side effects in children and adolescents with sJIA or pJIA

Side effects in children and adolescents with sJIA or pJIA are generally similar to those in adults. Some side effects are seen more often in children and adolescents: inflamed nose and throat, headache, feeling sick (nausea) and lower white blood cell counts.

Children and Adolescents

Tyenne pre-filled pen is not recommended for use in children under 12 years of age.

Tyenne must not be given to children with sJIA weighing less than 10 kg.

If a child has a history of *macrophage activation syndrome* (activation and uncontrolled proliferation of specific blood cells), tell your doctor. Your doctor will have to decide if they can still be given Tyenne.

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@sfd.gov.sa
Website: <https://ade.sfd.gov.sa/>

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



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