



# Your intravenous (IV) infusion treatment journey with **TYENNE<sup>®</sup>**



## Important Safety Information

### INDICATIONS

#### What does TYENNE treat?

TYENNE<sup>®</sup> (tocilizumab-aazg) is a prescription medicine called an interleukin-6 (IL-6) receptor antagonist.

TYENNE is used:

- To treat adults with moderately to severely active rheumatoid arthritis (RA) after at least one other medicine called a disease modifying antirheumatic drug (DMARD) has been used and did not work well
- To treat adults with giant cell arteritis (GCA)
- To treat patients with active polyarticular juvenile idiopathic arthritis (PJIA) 2 years of age and older
- To treat patients with active systemic juvenile idiopathic arthritis (SJIA) 2 years of age and older.

It is not known if TYENNE is safe and effective in children with PJIA or SJIA under 2 years of age or in children with conditions other than PJIA or SJIA.

#### TYENNE can cause serious side effects

##### Serious Infections

**TYENNE changes the way your immune system works. This can make you more likely to get infections or make any current infection worse. Some people have serious infections while taking TYENNE, including tuberculosis (TB), and infections caused by bacteria, fungi, or viruses that can spread throughout the body. Some people have died from these infections. Your healthcare provider should assess you for TB before starting and during treatment with TYENNE.**

Please see Important Safety Information throughout this brochure and accompanying full Prescribing Information and the Medication Guide, including Serious Side Effects, for TYENNE<sup>®</sup> (tocilizumab-aazg).

## **TYENNE® (tocilizumab-aazg) may help treat your uncontrolled signs and symptoms from rheumatoid arthritis (RA), giant cell arteritis (GCA), polyarticular juvenile idiopathic arthritis (PJIA), and systemic juvenile idiopathic arthritis (SJIA)**

Some of the signs and symptoms you may be experiencing, include<sup>1-4\*</sup>:

- ▶ Joint pain, stiffness, and swelling
- ▶ Fever
- ▶ Fatigue and weakness
- ▶ Unintended weight loss
- ▶ Persistent jaw pain, head pain, and scalp tenderness
- ▶ Vision loss or double vision

**If you are not receiving relief from your symptoms, ask your doctor if TYENNE® may be appropriate.**



\*The signs and symptoms listed span all product indications and will vary depending on your condition.

### **Important Safety Information (continued)**

Before starting TYENNE, tell your healthcare provider if you have:

- An infection, think you may have an infection, are being treated for an infection, or get a lot of infections that return. Symptoms of an infection, with or without a fever, include sweating or chills; shortness of breath; warm, red or painful skin or sores on your body; feeling very tired; muscle aches; blood in phlegm; diarrhea or stomach pain; cough; weight loss; burning when you urinate or urinating more than normal
- Any of the following conditions that may give you a higher chance of getting infections: diabetes, HIV, or a weak immune system
- Tuberculosis (TB), or have been in close contact with someone with TB
- live or have lived, or have traveled to certain parts of the United States where there is an increased chance of getting fungal infections. These parts include the Ohio and Mississippi River valleys and the Southwest
- hepatitis B or have had hepatitis B

#### **Who should not take TYENNE?**

Do not take TYENNE if you are allergic to tocilizumab products, or any of the ingredients in TYENNE.

**Be sure to talk to your healthcare provider if you see any signs of these serious side effects:**

#### **Tears (perforation) of the Stomach or Intestines**

If you have diverticulitis (inflammation in parts of the large intestine), talk to your healthcare provider before taking TYENNE. Some people taking TYENNE

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## What is TYENNE<sup>®</sup>5?

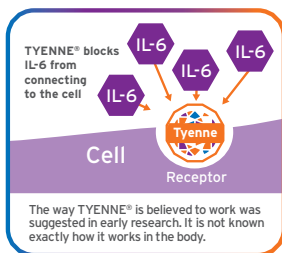
TYENNE<sup>®</sup> is an FDA-approved biosimilar medicine to Actemra<sup>®</sup> (tocilizumab) used to treat:

- ▶ Adults with moderately to severely active rheumatoid arthritis (RA) after at least one other medicine called a disease-modifying anti-rheumatic drug (DMARD) has been used and did not work well
- ▶ Adults with giant cell arteritis (GCA)
- ▶ People with active polyarticular juvenile idiopathic arthritis (PJIA) ages 2 years and above
- ▶ People with active systemic juvenile idiopathic arthritis (SJIA) ages 2 years and above

## How TYENNE<sup>®</sup> works<sup>5</sup>?

Interleukin (IL-6) is a messenger in your body that tells the immune system to attack harmful bacteria and viruses. When your body produces too much IL-6, it causes the immune system to attack your healthy cells and may contribute to the signs and symptoms of autoimmune diseases, like RA.

TYENNE<sup>®</sup> is designed to block IL-6 from activating the immune system to attack your healthy cells, which may have a positive effect that reduces symptoms.



### Important Safety Information (continued)

#### Tears (perforation) of the Stomach or Intestines (continued)

may develop a hole in the wall of their stomach or intestines (also known as a perforation). This happens most often in people who also take nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids, or methotrexate.

Tell your healthcare provider right away if you see any of these side effects: fever, stomach-area pain that does not go away, or if you see a change in your bowel habits.

#### Liver problems (Hepatotoxicity)

Some people have experienced serious life-threatening liver problems, which required liver transplant or led to death. Your healthcare provider may tell you to stop taking TYENNE if you develop new or worsening liver problems during treatment with TYENNE. Tell your healthcare provider right away if you have any of the following symptoms:





- feeling tired (fatigue)
- lack of appetite for several days or longer (anorexia)
- yellowing of your skin or the whites of your eyes (jaundice)
- abdominal swelling and pain on the right side of the stomach-area
- light colored stools
- weakness
- nausea and vomiting
- confusion
- dark "tea-colored" urine

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## What does it mean if your prescription medicine is an FDA-Approved biosimilar?

An FDA-approved biosimilar means that there are no clinically meaningful differences in effectiveness, safety, or purity between the biosimilar, like TYENNE®, and the reference (original product), like Actemra® (tocilizumab). Biosimilars are safe and effective<sup>5</sup>.

### TYENNE® and Actemra® are similar in the following ways<sup>5</sup>:

-  Made in the same type of cell line
-  Given the same way
-  Provide the same treatment benefits
-  Have the same potential side effects

However, biosimilars are different in an important aspect of care that impacts everyone – cost. Biosimilars, like TYENNE®, are less expensive than reference (original products), like Actemra®, which helps make critical medicines accessible to more patients.



**Biosimilars potentially offer up to 30% price reductions compared with reference products<sup>6</sup>**

#### Important Safety Information (continued)

##### Changes in Blood Test Results

Your healthcare provider should do blood tests before you start receiving TYENNE. If you have rheumatoid arthritis (RA) or giant cell arteritis (GCA), your healthcare provider should do blood tests 4 to 8 weeks after you start receiving TYENNE for the first 6 months and then every 3 months after that. If you have polyarticular juvenile idiopathic arthritis (PJIA) you will have blood tests done every 4 to 8 weeks during treatment. If you have systemic juvenile idiopathic arthritis (SJIA) you will have blood tests done every 2 to 4 weeks during treatment. These blood tests are to check for the following side effects of TYENNE:

- Low neutrophil count: neutrophils are white blood cells that help the body fight infection
- Low platelet count: platelets are blood cells that help with clotting, which stops bleeding
- Increase in liver function test levels
- Increase in blood cholesterol levels: your cholesterol levels should be checked 4 to 8 weeks after you start receiving TYENNE.

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## **TYENNE<sup>®</sup> is available as an intravenous (IV) infusion<sup>5</sup>**

TYENNE<sup>®</sup> is delivered as an intravenous (IV) infusion from a healthcare provider through a needle placed in a vein in your arm.

- ▶ The infusion will take about 1 hour
- ▶ For RA, GCA, or PJIA, you will receive a dose of TYENNE<sup>®</sup> about every 4 weeks
- ▶ For SJIA, you will receive a dose of TYENNE<sup>®</sup> about every 2 weeks

TYENNE<sup>®</sup> can be taken with other medications, such as methotrexate, non-steroidal anti-inflammatory drugs (NSAIDs), and prescription steroids, as instructed by your healthcare provider.



TYENNE<sup>®</sup> comes in a variety of vial sizes.

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### **Important Safety Information (continued)**

#### **Changes in Blood Test Results (continued)**

Your healthcare provider will determine how often you will have follow-up blood tests. Make sure you get all your follow-up blood tests done as ordered by your healthcare provider.

You should not receive TYENNE if your neutrophil and platelet counts are too low or your liver function test levels are too high. Changes in blood test results may cause your healthcare provider to stop your TYENNE treatment for a time or change your dose.

#### **Cancer**

TYENNE may increase your risk of certain cancers by changing the way your immune system works.

#### **Hepatitis B Infection**

If you have or are a carrier of the hepatitis B virus (a virus that affects the liver), the virus may become active while you use TYENNE. Your healthcare provider may do blood tests before you start treatment with TYENNE and while you are using TYENNE. Tell your healthcare provider if you have any signs of these symptoms:

#### **Serious Allergic Reactions**

Serious allergic reactions, including death, can happen with TYENNE. These reactions can happen with any infusion or injection of TYENNE, even if they

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# TYENNE® (tocilizumab-aazg) provides you access to KabiCare™, a comprehensive patient program to support you throughout your treatment journey

## Support Offerings



### Access to treatment

Assistance with navigating insurance to obtain coverage and reviewing patient benefits†



### Nurse Educators

Nurse educators are available to answer medical-related questions and provide injection training support for you and your caregivers‡



### Educational resources

Educational tools provide information on disease, medication, lifestyle modifications, and health and wellness

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## Important Safety Information (continued)

### Serious Allergic Reactions (continued)

did not occur with an earlier infusion or injection. Tell your healthcare provider before your next dose if you had hives, rash or flushing after your injection. Contact 911 immediately, as well as your healthcare provider, if you experience any of these reactions:

- shortness of breath or trouble breathing
- swelling of the lips, tongue, or face
- chest pain
- feeling dizzy or faint
- moderate or severe abdominal pain or vomiting

### Nervous System Problems

While rare, Multiple Sclerosis has been diagnosed in people who take TYENNE. It is not known what effect TYENNE may have on some nervous system disorders.

### What should I tell my healthcare provider before receiving TYENNE?

TYENNE may not be right for you. Before receiving TYENNE, tell your healthcare provider if you:

- have an infection
- have any stomach-area (abdominal) pain or been diagnosed with diverticulitis or ulcers in your stomach or intestines
- have liver problems
- have had a reaction to tocilizumab products or any of the ingredients in TYENNE before
- have or had a condition that affects your nervous system, such as multiple sclerosis

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## Financial support

KabiCare™ provides additional support programs to eligible patients.

### What type of insurance do you have?

#### Commercial or private insurance<sup>†</sup>

If you have commercial or private insurance, you may be eligible for the copay assistance program that lowers out-of-pocket costs to as little as \$0/month for TYENNE<sup>®</sup>, with an annual maximum.

#### Government insurance (Medicare/Medicaid)<sup>‡</sup>

If you have government insurance, but your plan does not cover TYENNE<sup>®</sup>, you may be eligible for assistance through the Patient Assistance Program (PAP) or through independent nonprofit patient assistance programs that may be able to help you afford TYENNE<sup>®</sup> copay costs.

#### Uninsured/Under-insured<sup>§</sup>

If you do not have insurance and/or cannot afford TYENNE<sup>®</sup>, you may be eligible for additional assistance through the Patient Assistance Program (PAP) or through independent nonprofit patient assistance programs.

#### Pay as little as \$0 copay for each dose of TYENNE<sup>®†</sup>

Ask your healthcare provider to help you enroll, if you qualify for copay assistance.

If you receive prescription reimbursement through your local, state, or federal government, visit [KabiCare.us](https://www.kabicare.us) or call **1.833.KABICARE** (1-833-522-4227).

<sup>†</sup> Eligibility criteria apply. Patients are not eligible for commercial copay assistance and Bridge to Therapy support if the prescription is eligible to be reimbursed, in the whole or in part, by any state or federal healthcare program.

<sup>‡</sup> Nurse support provided by KabiCare is not meant to replace discussions with a healthcare provider regarding a patient's care and treatment.

<sup>§</sup> Eligibility for resources provided by independent nonprofit patient assistance programs is based on the nonprofits' criteria, Fresenius Kabi has no control over these programs.

#### Important Safety Information (continued)

##### What should I tell my healthcare provider before receiving TYENNE? (continued)

- have recently received or are scheduled to receive a vaccine
- plan to have surgery or a medical procedure
- have any other medical conditions

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# Additional patient support and resources

We are committed to being your partner by providing support and resources for your journey with TYENNE® (tocilizumab-aazg)



Visit [TYENNE.com](http://TYENNE.com) to learn more

For product information, dosing instructions, and specific disease education, scan the QR code or visit the TYENNE® website.



[www.TYENNE.com](http://www.TYENNE.com)

## Important Safety Information (continued)

### What should I tell my healthcare provider before receiving TYENNE? (continued)

- plan to become pregnant or are pregnant. It is not known if TYENNE will harm your unborn baby.
- plan to breast-feed or are breast-feeding. You and your healthcare provider should decide if you will take TYENNE or breast-feed. You should not do both.
- are taking any medications, including prescription and nonprescription medicines, vitamins, and herbal supplements.

### The most common side effects of TYENNE include:

- upper respiratory tract infections (common cold, sinus infections)
- headache
- increased blood pressure (hypertension)
- injection site reactions

### TYENNE & Pregnancy

Tell your healthcare provider if you are planning to become pregnant, are pregnant, plan to breast-feed, or are breast-feeding. You and your healthcare provider should decide if you will take TYENNE or breast-feed. You should not do both.

Tell your healthcare provider if you have any side effects. You may report side effects to the FDA at 1-800-FDA-1088. You may also report side effects to Fresenius Kabi at 1-800-551-7176.

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## Understanding your intravenous (IV) infusion therapy

You have been prescribed a medication that will require an intravenous (IV) infusion. If you are new to IV therapy or have not received treatment before, it is a common delivery of medication and nothing to be worried about. The following information may be helpful in preparing you for your treatment.

### What is an IV infusion<sup>7</sup>?

IV infusion, or infusion therapy, is the delivery of medication through a needle or tube inserted into a vein. Your treatment can be delivered using gravity or a specialized pump to deliver the exact dose over a specified amount of time. This allows the medicine to enter your bloodstream right away.



IV therapy must be prepared by healthcare professionals prior to being administered, and once they are administered, the patient will be monitored to ensure that there are no adverse reactions.



Infusions are most commonly administered and supervised by registered nurses (RNs), nurse practitioners (NPs), or physicians (MD, DO) and given in a variety of settings, including some doctors' offices, outpatient infusion centers, and sometimes even in patients' homes.

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## Preparing for Your IV Infusion<sup>8</sup>

As you prepare for your treatment, you may want to talk with your care team about any side effects you may experience, possible interactions with your other medications, or any other concerns you may have. It's important to let your care team know about all other medicines and supplements that you are currently taking, or if you have had, or plan to have, any vaccinations.

You may need to have blood work or other testing done to make sure you don't have an infection and are healthy enough to receive your treatment.

If you are switching from a different medication, be sure to discuss the timing with your care team so you know when to stop the previous medication.

If you're sick, or have a fever or other signs of an infection, or have a recent or planned surgery, call your infusion center before your appointment as they may recommend rescheduling.

## Tips to help prepare for infusion day<sup>8</sup>

<b>Arrive Early</b>	Ask if you should arrive early for your appointment in case you need to complete any paperwork prior to your infusion.
<b>Plan your day</b>	Get a good night's sleep and bring activities to relax with. It may be a long day!
<b>Hydrate</b>	Drink plenty of fluids like water for a day or two before your appointment: this will hydrate you and can make your veins more easily accessible.
<b>Dress accordingly</b>	Dress accordingly. Treatment centers can be chilly. Wear layers or bring a blanket.
<b>Prepare for extra time</b>	The infusion usually lasts about an hour, but your total appointment time is usually longer so be prepared to sit for an extended period. You will receive your medicine in a comfortable reclining chair to allow you to relax during treatment.
<b>Bring a loved one or friend</b>	Some infusion centers allow you to have a visitor stay, but others do not. Check with your center if you plan to bring a guest.
<b>Schedule Transportation</b>	Make sure you are able to get to and from your appointment whether you have your own transportation or need to arrange for a ride.

## What to expect on infusion day

After you arrive, a nurse will check all your vital signs to make sure you're healthy enough to receive your infusion. Tell your nurse if you are experiencing cold, flu, or COVID-19 symptoms.

Your nurse will be able to give you an idea of how long the infusion will take once you are there and all set up. Typically, your medicine will be infused slowly for approximately one hour and the IV will remain in your arm for the duration of treatment.

The amount of medication you will receive is determined by your weight. It is common to be weighed before every infusion to ensure you are receiving a safe and effective dose.

It's important to speak up if you experience any side effects.



## Planning for your next appointment

It is important to get each dose of your medication as scheduled.

It's important to keep your scheduled appointments and get blood tests done as ordered, as well as address what to do about rescheduling. Routine lab monitoring is an important part of this therapy.

If you have questions or concerns about scheduling or keeping your next appointment, talk to your nurse or coordinator.

## Here is a checklist of helpful items you may want to bring or plan for during or after your infusion:

- Insurance card or documentation
  - Beverages and snacks
  - Comfortable clothing, including extra layers or a blanket
  - Books, tablets, games, or activities
  - Transportation to/from appointment
  - Questions for your care team
  - A list of dates for future appointments
-



# Infusion Access Foundation

Preparing  
for  
Treatment

Find an  
Infusion  
Center

Patient  
Support  
Programs



The Infusion Access Foundation (IAF) is dedicated to amplifying the voices of people living rare and chronic disease to ensure people have access to provider-administered therapies when and where they need them.

[infusionaccessfoundation.org](https://infusionaccessfoundation.org)



SCAN ME

**Scan the QR code to access an educational video on how to prepare for your infusion.**

Nothing contained in this brochure shall be construed to imply endorsement or sponsorship by Infusion Access Foundation of TYENNE® or any other Fresenius Kabi products, nor discrimination against similar brands or products not mentioned. Financial support for development of the educational portion of this brochure regarding IV infusion therapy was provided by Fresenius Kabi to Infusion Access Foundation.

**References:** **1.** Rheumatoid arthritis: Symptoms, diagnosis, and treatment: Arthritis foundation. [www.arthritis.org](http://www.arthritis.org). October 15, 2021. Accessed February 21, 2024. <https://www.arthritis.org/diseases/rheumatoid-arthritis>. **2.** Juvenile idiopathic arthritis (JIA): Arthritis foundation. [www.arthritis.org](http://www.arthritis.org). Accessed February 21, 2024. <https://www.arthritis.org/diseases/juvenile-idiopathic-arthritis>. **3.** Systemic juvenile idiopathic arthritis: Arthritis foundation. [www.arthritis.org](http://www.arthritis.org). Accessed February 21, 2024. <https://www.arthritis.org/diseases/systemic-juvenile-idiopathic-arthritis>. **4.** Giant Cell Arteritis. Mayo Clinic. September 21, 2022. Accessed February 21, 2024. <https://www.mayoclinic.org/diseases-conditions/giant-cell-arteritis/symptoms-causes/syc-20372758>. **5.** TYENNE Prescribing Information: Fresenius Kabi, 2024. **6.** Kabir ER, Moreino SS, Siam MKS. The breakthrough of biosimilars: A twist in the narrative of biological therapy. *Biomolecules*. 2019;9(9):410. <https://pubmed.ncbi.nlm.nih.gov/3145>. **7.** Infusion therapy: Frequently asked questions. National Infusion Center Association. August 25, 2020. Accessed March 4, 2024. <https://infusioncenter.org/faqs/>. **8.** Welker M. IV Drug Infusion FAQs: Guidelines, treatment, conditions. [www.medicinenet.com](http://www.medicinenet.com). September 2, 2016. Accessed February 21, 2024. [https://www.medicinenet.com/iv\\_drug\\_infusion\\_faqs/article.htm#how\\_do\\_i\\_prepare\\_for\\_the\\_infusion](https://www.medicinenet.com/iv_drug_infusion_faqs/article.htm#how_do_i_prepare_for_the_infusion).