

INDICATIONS

What does TYENNE treat?

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

TYFNNF 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.



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

Some of the signs and symptoms you may be experiencing include 1-4:

- Joint pain, stiffness, and swelling
- Fatigue and weakness
- Persistent jaw pain, head pain, and scalp tenderness
- Fever
- Unintended weight loss
- 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





What is TYENNE®5?

TYENNE® is an FDA-approved biosimilar medicine to Actemra® (tocilizumab) 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
- Adults with giant cell arteritis (GCA)
- People 2 years and above with active polyarticular juvenile idiopathic arthritis (PJIA)
- People 2 years and above with active systemic juvenile idiopathic arthritis (SJIA)

For RA, PJIA, and SJIA, TYENNE® can be taken with or without disease-modifying antirheumatic drugs (DMARDs), like methotrexate.†

[†]Not recommended for concomitant use with biological DMARDs.

Important Safety Information (continued)

- 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.

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® (tocilizumab-aazg), and the reference (original product), like Actemra® (tocilizumab). Biosimilars are safe and effective⁵.

TYENNE® and Actemra® are similar in the following ways5:



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 products⁶

Important Safety Information (continued)

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 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.

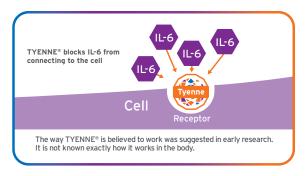
Tell your healthcare provider right away if you see any of these side effects: fever, stomach-area pain that does not go away, or if you see a change in your bowel habits.



How does TYENNE® work5?

Interleukin-6 (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® 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)

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 eves (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

TYENNE® (tocilizumab-aazg) injection options are designed for your ease-of-use⁵

You've been prescribed TYENNE®, which is available as a single-dose prefilled autoinjector and a single-dose prefilled syringe.

Administering TYENNE®



Prepare

- · Find a comfortable, clean, flat surface
- Examine the device for damage or expiration
- · Wash your hands prior to injection



Inject

- Choose the injection site (stomach or front of thighs)
- · Select a different site for each new injection
- · Make sure the injection area is clean
- · Give your injection



Dispose and Record

- Properly dispose of the device and supplies in a sharps container
- · Document the injection site and date of therapy

Talk to your healthcare provider if you or your caregiver have any questions about TYENNE®.

Important Safety Information (continued)

Changes in Blood Test Results

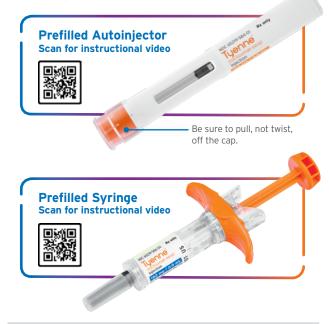
Your healthcare provider should do blood tests before you start receiving TYENNE. If you have rheumatoid arthritis (RA) or giant cell arteritis (GCA), your healthcare provider should do blood tests 4 to 8 weeks after you start receiving TYENNE for the first 6 months and then every 3 months after that. 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



Administering TYENNE® using the subcutaneous injection devices

Please note that TYENNE®'s autoinjector is different from Actemra®'s autoinjector. Also, **remember** to always follow your healthcare provider's advice and read the FDA-approved Instructions for Use that come with your TYENNE® device. If you need additional guidance, visit www.tyenne.com for videos and printed instructions.



Important Safety Information (continued)

Changes in Blood Test Results (continued)

- · 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.

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.



Storage and Handling⁵

- Keep TYENNE® (tocilizumab-aazg) in the original carton to protect from light and store it in a refrigerator set at 36°F to 46°F (2°C to 8°C).
- Prior to use, remove the prefilled syringe or autoinjector from the refrigerator and allow to sit at room temperature outside of the carton for 30 minutes (prefilled syringe) or 45 minutes (autoinjector). Do not warm TYENNE® in any other way.
- TYENNE® may be stored at room temperature at or below 77°F (25°C) in the original carton for up to 14 days.



Important Safety Information (continued)

Cance

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:

- · feel very tired
- skin or eyes look yellow
- · little or no appetite
- vomitina
- · clay-colored bowel movements
- · fevers

- chills
- stomach discomfort
- · muscle aches
- · dark urine
- skin rash



Common things to note about your subcutaneous treatment with TYENNE®

Whether it is your first injection, or you have been on treatment for a while, there are a few things that you may experience during treatment:



Routine blood tests⁵ - Your care team will test your blood prior to your first treatment and will determine how often you will have follow-up blood tests. The tests will check your liver function, neutrophil levels, platelet counts, and cholesterol. These tests are common with all patients.



Weighing in during office appointments - Since TYENNE® is a weight-based treatment, your care team will weigh you at in-office appointments to make sure you are receiving the appropriate dose.



Side effects - As with all medications, you may be at risk of experiencing sides effects after your injection. Make sure to keep an eye out and contact your nurse or physician for medical advice about side effects.

Important Safety Information (continued)

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 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 91 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

Fresenius Kabi provides you access to KabiCare™, a comprehensive patient support program

KabiCare[™] offers wide-ranging resources to supplement your experience with TYENNE[®]. Your healthcare provider can enroll you in KabiCare[™] at no cost.

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



To learn more about the KabiCare™ patient support program, please scan the QR code or visit www.kabicare.us.



Important Safety Information (continued)

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



Financial support

KabiCare™ provides additional support programs to eligible patients.

What type of insurance do you have?

Commercial or private insurance[‡]

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®, with an annual maximum.

Government insurance (Medicare/Medicaid)||

If you have government insurance, but your plan does not cover TYENNE®, 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® copay costs.

Uninsured/ Under-insured

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

Pay as little as \$0 copay for each dose of TYENNE®#

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** or call **1.833.KABICARE** (1-833-522-4227).

- *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.
- [§] Nurse support provided by KabiCare is not meant to replace discussions with a healthcare provider regarding a patient's care and treatment.
- 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)

- 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



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 to learn more

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



www.TYENNE.com

References: 1. Rheumatoid arthritis: Symptoms, diagnosis, and treatment: Arthritis foundation. 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. Accessed February 21, 2024. https://www.arthritis.org/diseases/juvenile-idiopathic-arthritis. 3. Systemic juvenile-idiopathic arthritis: Arthritis foundation. 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/qiant-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.

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

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