



Continue Moving. Continue Forward.

Get to know AVTOZMA, an FDA-approved interchangeable biosimilar to Actemra[®] (tocilizumab)

AVTOZMA is a prescription medicine 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 and above
- People with **active systemic juvenile idiopathic arthritis (SJIA)** ages 2 and above
- People ages 2 years and above who experience severe or life-threatening **Cytokine Release Syndrome (CRS)** following chimeric antigen receptor (CAR) T-cell treatment
- Hospitalized adults with **coronavirus disease 2019 (COVID-19)** receiving systemic corticosteroids and requiring supplemental oxygen or mechanical ventilation. AVTOZMA is not approved for subcutaneous use in people with COVID-19.

It is not known if AVTOZMA 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.

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

FDA, Food and Drug Administration.

IMPORTANT SAFETY INFORMATION

AVTOZMA can cause serious side effects, including:

Serious infections, which may lead to death. AVTOZMA can weaken your immune system, increasing the risk of infections or worsening existing ones. Your doctor will test for tuberculosis (TB) before starting treatment. If you have COVID-19, your doctor should monitor you for signs and symptoms of new infections during and after treatment with AVTOZMA. After starting AVTOZMA, call your doctor right away if you have any symptoms of an infection such as fever, chills, cough, or other signs of infection.

What is AVTOZMA?

AVTOZMA is a prescription biosimilar



AVTOZMA is a biosimilar of Actemra®. Biosimilar means that:

- A biologic product is approved based on data demonstrating that it is highly similar to an FDA-approved biological product, known as a reference product
- There are no clinically meaningful differences in how it works or in how safe it is compared to the reference product

A biosimilar is typically more affordable than the reference product.

Since AVTOZMA is a biosimilar of Actemra, it can be used instead of Actemra. Some biosimilars, including AVTOZMA, are considered “interchangeable,” which means they can be substituted without changing your prescription.



AVTOZMA, like Actemra, works by blocking a protein in your body called interleukin-6 (IL-6)

IL-6 can cause inflammation, leading to pain, swelling, and other symptoms. AVTOZMA works by stopping IL-6, which helps reduce inflammation.

What does AVTOZMA treat?

AVTOZMA is prescribed to treat these immune-related conditions:



Rheumatoid arthritis (RA). RA is a long-term condition that causes pain, swelling, and inflammation in the joints. RA is an autoimmune disease, which means the immune system mistakenly attacks the body’s healthy tissues.



Giant cell arteritis (GCA). GCA is a condition where the lining of the arteries becomes inflamed. It usually affects the arteries in the head, especially around the temples. Common symptoms include headaches, scalp tenderness, pain in the jaw, and problems with vision.



Polyarticular juvenile idiopathic arthritis (PJIA). PJIA is a type of arthritis in children that can cause lasting pain, swelling, and stiffness in many different joints.



Systemic juvenile idiopathic arthritis (SJIA). SJIA is another type of arthritis in children where other parts of the body are affected before the joints are.



Cytokine release syndrome (CRS). CRS is a potential side effect after CAR T-cell therapy. It happens when the immune system releases too many proteins called cytokines, which are responsible for coordinating the body’s immune response. CRS may cause fever, chills, tiredness, or low blood pressure, and can become severe or life-threatening.



Coronavirus disease 2019 (COVID-19). COVID-19 is a respiratory illness caused by a coronavirus. COVID-19 can lead to serious illness, including breathing problems.

IMPORTANT SAFETY INFORMATION continued

Tears (perforation) in your stomach or intestines. Some people taking AVTOZMA get tears in their stomach or intestine. This happens most often in people who also take nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids, or methotrexate. Get medical help right away if you have stomach pain that does not go away, and a change in your bowel habits.

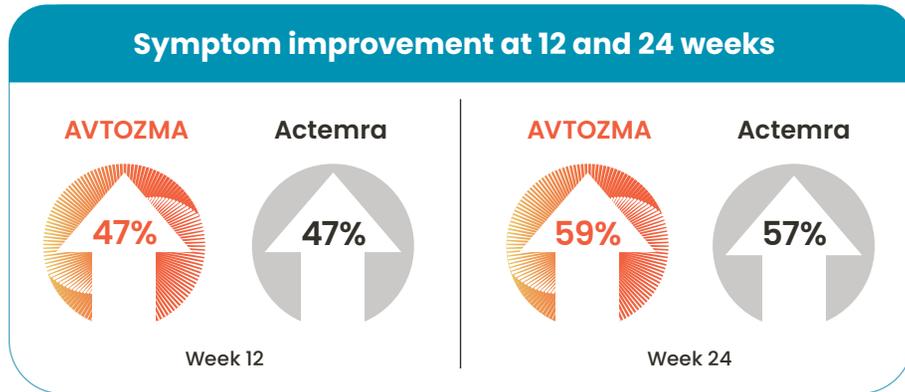
IMPORTANT SAFETY INFORMATION continued

Liver problems. Some people have experienced serious life-threatening liver problems, which required a liver transplant or led to death. Your doctor will monitor your liver function. Call your doctor if you experience tiredness, loss of appetite, nausea, dark urine, or yellowing of the skin or eyes.

How AVTOZMA can help

AVTOZMA was shown to be as effective and safe as Actemra®

In a clinical study of 471 patients with moderate to severe rheumatoid arthritis (RA), AVTOZMA was shown to be as effective as Actemra in improving symptoms.



Individual results may vary. See the Medication Guide for full uses of AVTOZMA.

People taking AVTOZMA and Actemra saw similar improvement in symptoms. To show improvement, doctors measure a “disease activity score” based on things like swollen joints, how you feel, and blood tests. In a clinical study, AVTOZMA and Actemra showed a 47% improvement in symptoms based on the disease activity score. At 24 weeks, AVTOZMA showed a 59% improvement and Actemra showed a 57% improvement. **This means the disease became less active and both groups saw similar improvements in RA symptoms.**

After one year of treatment, AVTOZMA and Actemra improved symptoms about the same amount. AVTOZMA improved symptoms by 67% and Actemra by 66%.

IMPORTANT SAFETY INFORMATION continued

Changes in certain laboratory test results. Your doctor should do blood tests before and during treatment with AVTOZMA. Make sure you get all your follow-up blood tests done as ordered by your doctor. Your doctor may stop your AVTOZMA treatment for a period of time or change your dose of medicine if needed because of changes in these blood test results.



AVTOZMA is approved to treat other diseases it has not been directly tested on in studies. The FDA looks at a wide variety of tests and data to determine that a drug is biosimilar to a reference product, including clinical trials, blood and immune system evaluations, and chemical analyses. AVTOZMA passed these tests and is officially approved by the FDA as a biosimilar to Actemra.

In the same clinical trial, AVTOZMA was found to be as safe and well tolerated as Actemra.



Models are used for illustrative purposes only. Not actual patients.

Side effects of AVTOZMA

AVTOZMA can cause serious side effects

Serious infections

Some people have serious infections while taking AVTOZMA, including tuberculosis (TB) and infections caused by bacteria, fungi, or viruses. These infections can sometimes lead to hospitalization or death.

Your healthcare provider should assess you for TB before starting, during, and after treatment with AVTOZMA (unless you have COVID-19).

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

- an infection, get a lot of infections, or have infections that keep coming back
- TB or if you have been in contact with someone with TB, or if you have traveled where there is an increased risk of TB
- have diabetes
- have or have had hepatitis B
- live, have lived, or have traveled to places where there is an increased risk of fungal infections
- any conditions that weaken your immune system

If you have COVID-19, your healthcare provider should monitor you for signs and symptoms of new infections during and after treatment with AVTOZMA.

Before starting AVTOZMA, please review the attached Medication Guide, including “What is the most important information I should know about AVTOZMA?” or go to www.avtozma.com

Other serious side effects

Treatment with AVTOZMA can sometimes lead to other serious side effects such as:

- Tears in the stomach or intestines
- Liver problems
- Changes in blood test results
- Cancer
- Hepatitis B infection
- Serious allergic reactions
- Nervous system problems

Common side effects include

- Upper respiratory tract infections, such as the common cold or sinus infections
- Headache
- High blood pressure (hypertension)
- Injection site reactions

These are not all of the possible side effects of AVTOZMA.

Call your doctor for medical advice about side effects.

You may report side effects to FDA at 1-800-FDA-1088.

You may also report side effects to Celltrion USA, Inc. at 1-800-560-9414.

IMPORTANT SAFETY INFORMATION

AVTOZMA can cause serious side effects, including:

Serious infections, which may lead to death. AVTOZMA can weaken your immune system, increasing the risk of infections or worsening existing ones. Your doctor will test for tuberculosis (TB) before starting treatment. If you have COVID-19, your doctor should monitor you for signs and symptoms of new infections during and after treatment with AVTOZMA. After starting AVTOZMA, call your doctor right away if you have any symptoms of an infection such as fever, chills, cough, or other signs of infection.

Tears (perforation) in your stomach or intestines. Some people taking AVTOZMA get tears in their stomach or intestine. This happens most often in people who also take nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids, or methotrexate. Get medical help right away if you have stomach pain that does not go away, and a change in your bowel habits.

Liver problems. Some people have experienced serious life-threatening liver problems, which required a liver transplant or led to death. Your doctor will monitor your liver function. Call your doctor if you experience tiredness, loss of appetite, nausea, dark urine, or yellowing of the skin or eyes.

Changes in certain laboratory test results. Your doctor should do blood tests before and during treatment with AVTOZMA. Make sure you get all your follow-up blood tests done as ordered by your doctor. Your doctor may stop your AVTOZMA treatment for a period of time or change your dose of medicine if needed because of changes in these blood test results.

Cancer. AVTOZMA may increase your risk of certain cancers by changing the way your immune system works. Tell your doctor if you have ever had any type of cancer.

Do not take AVTOZMA if you are allergic to tocilizumab or any of its ingredients.

Before taking AVTOZMA, tell your doctor about all your medical conditions, including if you:

- Have infections (with or without a fever), liver problems, or a history of stomach/intestinal ulcers or cancer.
- Have diabetes, HIV, or a weak immune system. People with these conditions have a higher chance for infections.
- Have or had hepatitis B, tuberculosis (TB), have been in close contact with someone with TB, live or have lived or traveled to certain parts of the country (such as the Ohio and Mississippi River valleys and the Southwest).
- Have had an allergic reaction to tocilizumab products or any of its ingredients.
- Have or had a condition that affects your nervous system, such as multiple sclerosis.
- Have had a recent or scheduled vaccine (you should not receive live vaccines while on AVTOZMA).
- Plan to receive surgery or a medical procedure.
- Are pregnant, planning to become pregnant, or breastfeeding. AVTOZMA may harm your unborn baby. It is not known if AVTOZMA passes into your breast milk.

Also, tell your doctor about all of the medicines you take, including prescription, over-the-counter medicines, vitamins and herbal supplements. AVTOZMA and other medicines may affect each other causing side effects. Know the medicines you take. Keep a list of them to show to your healthcare provider and pharmacist when you get a new medicine.

The most common side effects include: upper respiratory tract infections (such as colds), headache, high blood pressure, and injection site reactions.

These are not all the possible side effects. Call your doctor right away if you have any symptoms of an infection or experience any side effects.

You may report side effects by calling Celltrion USA Inc. at 1-800-560-9414, FDA at 1-800-FDA-1088, or visit www.fda.gov/medwatch.

How AVTOZMA is administered

Subcutaneous (SC) injection administration

AVTOZMA may be given as an injection under your skin. SC injections are given from a single-dose prefilled autoinjector at home by you or a caregiver.



AVTOZMA injections—what you need to know

- Before self-injecting AVTOZMA, your healthcare provider will train you or your caregiver on how to use the prefilled autoinjector
- AVTOZMA is injected under the skin into fatty tissue (the stomach area [abdomen], upper thigh, or upper arm), and not into muscle
- Total administration time for AVTOZMA is 50 minutes
 - The prefilled autoinjector needs 45 minutes to warm up
 - It takes about 5 minutes to prepare, inject, and dispose of the prefilled autoinjector
 - Your dosing frequency depends on what you are treated for

IMPORTANT SAFETY INFORMATION continued

Cancer. AVTOZMA may increase your risk of certain cancers by changing the way your immune system works. Tell your doctor if you have ever had any type of cancer.

Do not take AVTOZMA if you are allergic to tocilizumab or any of its ingredients.

Intravenous (IV) administration

AVTOZMA may also be given as an IV infusion at a healthcare facility.



AVTOZMA infusions—what you need to know

- AVTOZMA infusions are administered at a healthcare facility by a trained medical professional
- A nurse or tech will start by inserting an IV line into your arm or hand
- Medication will enter the bloodstream, and the infusion takes about an hour
- IV infusions do not usually cause pain, but you may feel a slight pinch when your healthcare professional inserts the IV
- Infusions take place in an infusion room, where you can relax and watch TV, read, or rest

Serious allergic reactions can happen with AVTOZMA SC injection or IV infusion. Stop taking AVTOZMA and get emergency help right away if you start to experience any serious allergic reaction, including:

- Trouble breathing or wheezing
- Swelling of the face, lips, mouth, or tongue
- Feeling dizzy or faint
- Fast heartbeat or pounding in your chest (tachycardia)
- Sweating

IMPORTANT SAFETY INFORMATION continued

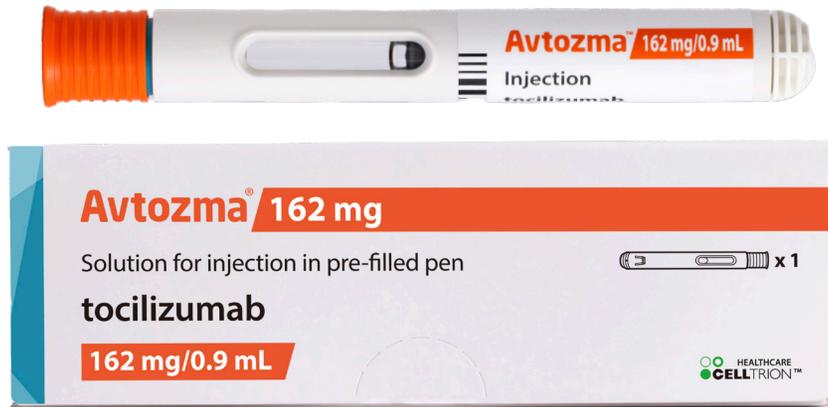
Before taking AVTOZMA, tell your doctor about all your medical conditions, including if you:

- Have infections (with or without a fever), liver problems, or a history of stomach/intestinal ulcers or cancer.

Designed for efficient administration

AVTOZMA is available in a single-dose, prefilled autoinjector that offers you the flexibility and control of self-administration

You'll be shown how to use the prefilled autoinjector by your doctor or a trained nurse, so you or a caregiver can inject AVTOZMA at home.



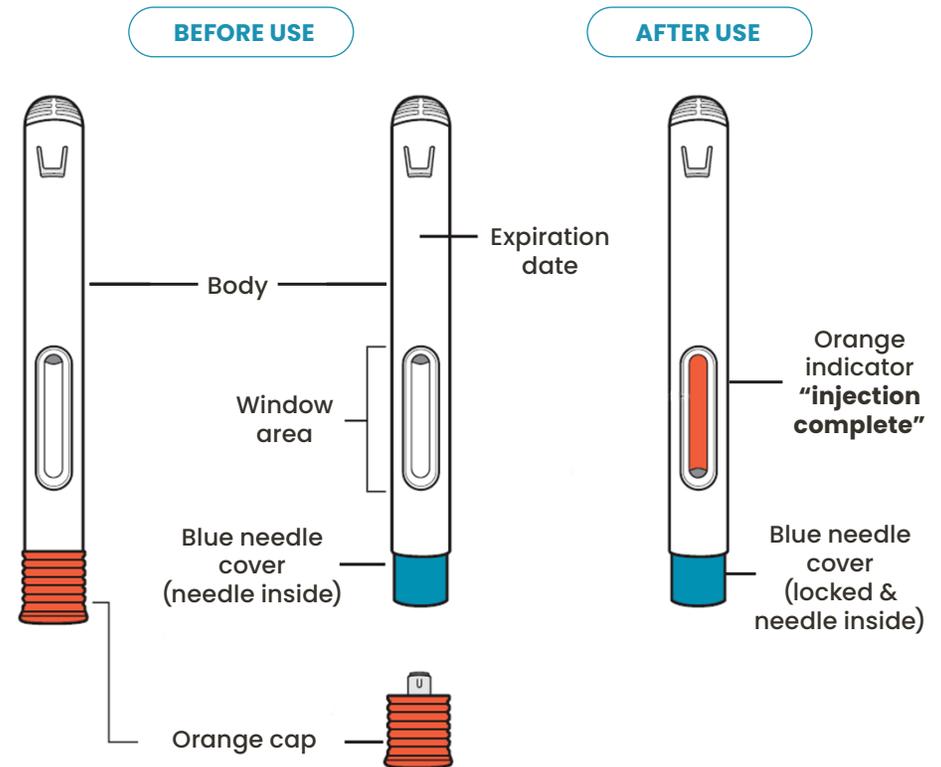
Do not try to inject AVTOZMA by yourself until you or your caregiver has been shown how to inject AVTOZMA by your doctor or nurse.

IMPORTANT SAFETY INFORMATION continued

Before taking AVTOZMA, tell your doctor about all your medical conditions, including if you:

- Have diabetes, HIV, or a weak immune system. People with these conditions have a higher chance for infections.
- Have or had hepatitis B, tuberculosis (TB), have been in close contact with someone with TB, live or have lived or traveled to certain parts of the country (such as the Ohio and Mississippi River valleys and the Southwest).

The AVTOZMA prefilled autoinjector is a single-use, prefilled device that delivers AVTOZMA with the push of a button. The prefilled autoinjector is designed to keep the needle tip covered until you inject, and the needle is automatically shielded after the injection is complete.



IMPORTANT SAFETY INFORMATION continued

- Have had an allergic reaction to tocilizumab products or any of its ingredients.
- Have or had a condition that affects your nervous system, such as multiple sclerosis.

Dosing for AVTOZMA

Dosing for patients being treated with AVTOZMA

The starting dose for AVTOZMA is based on what you are being treated for.

Approved Uses for AVTOZMA	Recommended SC Dosing	Recommended IV Dosing
RA in adult patients	162 mg every other week, with a potential increase to every week in patients weighing <100 kg 162 mg weekly in patients weighing ≥100 kg	4 mg/kg every 4 weeks, with a potential increase to 8 mg/kg every 4 weeks, depending on how you respond to treatment
GCA in adult patients	162 mg weekly with glucocorticoids (for example, prednisone), slowly decreasing over time. AVTOZMA can be used alone after stopping glucocorticoids	6 mg/kg every 4 weeks with glucocorticoids (for example, prednisone), slowly decreasing over time. AVTOZMA can be used alone after stopping glucocorticoids

Approved Uses for AVTOZMA	Recommended SC Dosing	Recommended IV Dosing
Active PJIA in pediatric patients	162 mg every 3 weeks in patients weighing <30 kg 162 mg every 2 weeks in patients weighing ≥30 kg	10 mg/kg every 4 weeks in patients weighing <30 kg 8 mg/kg every 4 weeks in patients weighing ≥30 kg
Active SJIA in pediatric patients	162 mg every 2 weeks in patients weighing <30 kg 162 mg weekly in patients weighing ≥30 kg	12 mg/kg every 2 weeks in patients weighing <30 kg 8 mg/kg every 2 weeks in patients weighing ≥30 kg

IMPORTANT SAFETY INFORMATION continued

- Have had a recent or scheduled vaccine (you should not receive live vaccines while on AVTOZMA).
- Plan to receive surgery or a medical procedure.
- Are pregnant, planning to become pregnant, or breastfeeding. AVTOZMA may harm your unborn baby. It is not known if AVTOZMA passes into your breast milk.

AVTOZMA can be taken alone or with other RA medicines to help reduce joint pain and swelling*

Many people with RA take methotrexate with or without other disease-modifying anti-rheumatic drugs (DMARDs). AVTOZMA is another treatment option for RA that can be used either on its own or in combination with methotrexate or other DMARDs.

The active ingredient in AVTOZMA, tocilizumab, has been studied in 5 clinical trials to show that it works well and is safe.



*AVTOZMA can be taken alone for giant cell arteritis after slowly lowering the dose of steroids; AVTOZMA can also be taken alone or with other approved medications for polyarticular juvenile idiopathic arthritis and systemic juvenile idiopathic arthritis.

GCA, giant cell arteritis; IV, intravenous; PJIA, polyarticular juvenile idiopathic arthritis; RA, rheumatoid arthritis; SC, subcutaneous; SJIA, systemic juvenile idiopathic arthritis.

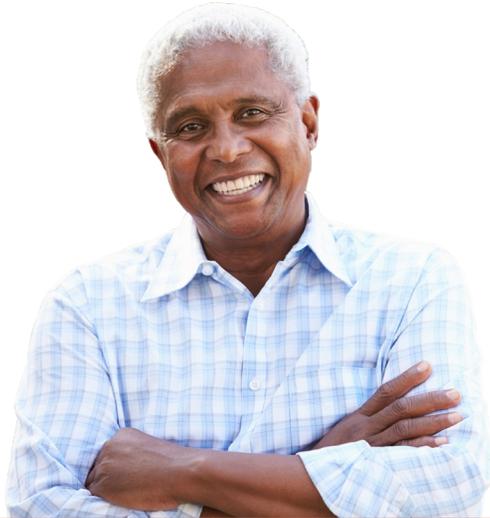
IMPORTANT SAFETY INFORMATION continued

Also, tell your doctor about all of the medicines you take, including prescription, over-the-counter medicines, vitamins and herbal supplements. AVTOZMA and other medicines may affect each other causing side effects. Know the medicines you take. Keep a list of them to show to your healthcare provider and pharmacist when you get a new medicine.

Starting AVTOZMA

Before you start treatment

If you have any questions about your treatment with AVTOZMA, including possible side effects, be sure to ask your doctor.



Before and during treatment, your doctor may do blood tests to make sure your liver is healthy and to check your white blood cells, platelets, and cholesterol levels.

IMPORTANT SAFETY INFORMATION *continued*

The most common side effects include: upper respiratory tract infections (such as colds), headache, high blood pressure, and injection site reactions.

These are not all the possible side effects. Call your doctor right away if you have any symptoms of an infection or experience any side effects.

You may report side effects by calling Celltrion USA Inc. at 1-800-560-9414, FDA at 1-800-FDA-1088, or visit www.fda.gov/medwatch.

Celltrion support programs

These programs help you get better access to AVTOZMA

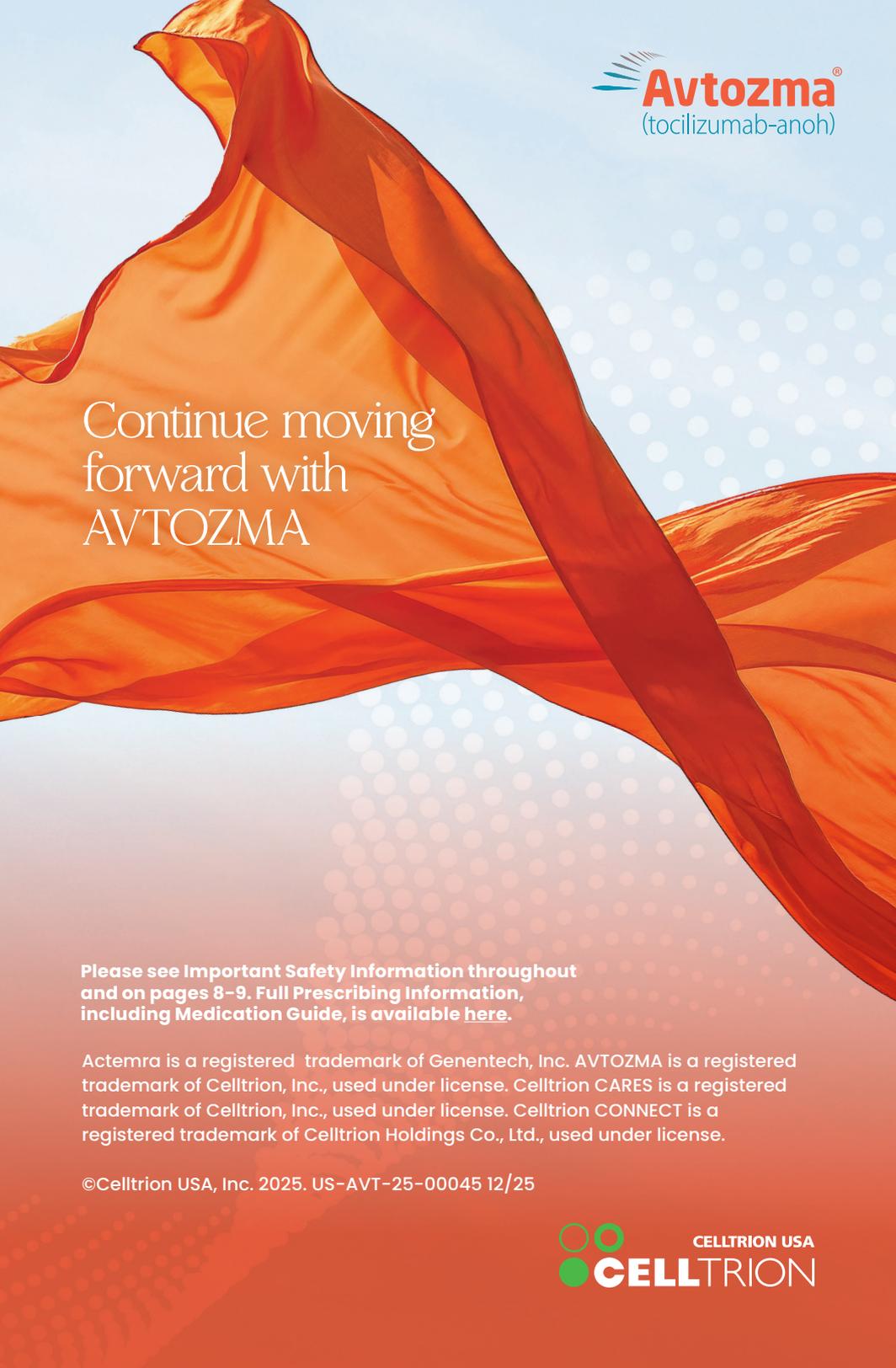


Help verify your insurance coverage for AVTOZMA, determine your plan-specific requirements, and understand your available benefits.



Connect with Celltrion CARES® for co-pay assistance with your commercial insurance.





Continue moving
forward with
AVTOZMA

Please see Important Safety Information throughout and on pages 8-9. Full Prescribing Information, including Medication Guide, is available [here](#).

Actemra is a registered trademark of Genentech, Inc. AVTOZMA is a registered trademark of Celltrion, Inc., used under license. Celltrion CARES is a registered trademark of Celltrion, Inc., used under license. Celltrion CONNECT is a registered trademark of Celltrion Holdings Co., Ltd., used under license.

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