

**Tofidence**<sup>®</sup>  
(tocilizumab-bavi)  
injection, for intravenous use 20 mg/mL

## Your guide to IV treatment with TOFIDENCE, a biosimilar to ACTEMRA (tocilizumab)\*

\*ACTEMRA is also available in a subcutaneous (under the skin) formulation.

IV, intravenous.

### What is TOFIDENCE?

TOFIDENCE is a prescription medicine called an Interleukin-6 (IL-6) receptor antagonist.

TOFIDENCE is 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.
- To treat adults with giant cell arteritis (GCA).
- To treat people with active polyarticular juvenile idiopathic arthritis (PJIA) ages 2 and above.
- To treat people with active systemic juvenile idiopathic arthritis (SJIA) ages 2 and above.
- To treat hospitalized adults with coronavirus disease 2019 (COVID-19) receiving systemic corticosteroids and requiring supplemental oxygen or mechanical ventilation.

It is not known if TOFIDENCE 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.

### IMPORTANT SAFETY INFORMATION

#### What is the most important information I should know about TOFIDENCE?

##### TOFIDENCE can cause serious side effects including Serious Infections:

- TOFIDENCE is a medicine that affects your immune system. TOFIDENCE can lower the ability of your immune system to fight infections. Some people have serious infections while taking TOFIDENCE, 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 TOFIDENCE (except if you have COVID-19).

Please read the [Medication Guide](#) for TOFIDENCE, including the information about serious infections, and discuss it with your doctor. The Physician [Prescribing Information](#) also is available.

Please see additional Important Safety Information on [pages 3-5](#).



Dare to move forward.  
Our commitment is all in.



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## **IMPORTANT SAFETY INFORMATION (continued)**

### **What is the most important information I should know about TOFIDENCE (tocilizumab-bavi)? (continued)**

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

- You should not start taking TOFIDENCE if you have any kind of infection unless your healthcare provider says it is okay.

### **What should I tell my doctor BEFORE taking TOFIDENCE?**

#### **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 fever, may 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.
- Diabetes, HIV, or a weak immune system.
- TB or have been in close contact with someone with TB.
- Lived or live or have traveled to certain parts of the country (such as the Ohio and Mississippi River valleys and the Southwest) where there is an increased chance for getting certain kinds of fungal infections.
- Had hepatitis B or have hepatitis B.

### **What should I watch for AFTER starting TOFIDENCE?**

#### **Contact your healthcare provider right away if you have any symptoms of an infection or signs of these serious side effects:**

##### **• Tears (perforations) of the Stomach or Intestines**

Talk to your healthcare provider if you have had diverticulitis (inflammation in parts of the large intestine) or ulcers in your stomach or intestines. Some people taking TOFIDENCE get tears in their stomach or intestine. 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 have fever and new onset stomach-area pain that does not go away, and a change in your bowel habits.

##### **• Liver Problems (Hepatotoxicity)**

Some people have experienced serious life-threatening liver problems, which required a liver transplant or led to death. Your healthcare provider may tell you to stop taking TOFIDENCE if you develop new or worse liver problems during treatment with TOFIDENCE. 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 your stomach-area.

## IMPORTANT SAFETY INFORMATION (*continued*)

### • **Liver Problems (Hepatotoxicity) (*continued*)**

- light colored stools.
- weakness.
- nausea and vomiting.
- confusion.
- dark “tea-colored” urine.

### • **Changes in Laboratory Test Results**

Your healthcare provider should do blood tests before you start receiving TOFIDENCE (tocilizumab-bavi). If you have rheumatoid arthritis (RA) or giant cell arteritis (GCA) your healthcare provider should do blood tests every 4 to 8 weeks after you start receiving TOFIDENCE 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 TOFIDENCE:

- low neutrophil count. Neutrophils are white blood cells that help the body fight off bacterial infections.
- low platelet count. Platelets are blood cells that help with blood clotting and stop bleeding.
- increase in certain liver function tests.
- increase in blood cholesterol levels. Your cholesterol levels should be checked 4 to 8 weeks after you start receiving TOFIDENCE.

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 TOFIDENCE if your neutrophil or platelet counts are too low or your liver function tests are too high. Changes in test results may cause your healthcare provider to stop your TOFIDENCE treatment for a period of time or change your dose.

### • **Cancer**

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

### • **Hepatitis B Infection**

If you are a carrier of the hepatitis B virus (a virus that affects the liver), the virus may become active while you use TOFIDENCE. Your healthcare provider may do blood tests before you start treatment with TOFIDENCE and while you are using TOFIDENCE. Tell your healthcare provider if you have any of the following symptoms: feel very tired; vomiting; chills, dark urine; skin or eyes look yellow; clay-colored bowel movements; stomach discomfort; skin rash, little or no appetite; fevers; muscle aches.

## IMPORTANT SAFETY INFORMATION (*continued*)

- **Serious Allergic Reactions**

Serious allergic reactions, including death, can happen with TOFIDENCE (tocilizumab-bavi). These reactions can happen with any infusion of TOFIDENCE, even if they did not occur with an earlier infusion. Stop taking TOFIDENCE, contact your healthcare provider, and get emergency help right away if you have any of the following signs of a serious allergic reaction: trouble breathing; swelling of your mouth, lips, tongue, or face; wheezing; severe itching; skin rash, hives, redness, or swelling outside of the injection site area; dizziness or fainting; fast heartbeat or pounding in your chest (tachycardia); sweating.

- **Nervous System Problems**

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

**Most common side effects of TOFIDENCE include:** upper respiratory tract infections (common cold, sinus infections), headache, and increased blood pressure (hypertension).

Tell your healthcare provider about any side effect that bothers you or does not go away. These are not all the possible side effects of TOFIDENCE.

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

**This is the most important information to know about TOFIDENCE. For more information, talk to your healthcare provider.**

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.**

**Please read the [Medication Guide for TOFIDENCE](#), including the information about serious infections, and discuss it with your doctor. The Physician [Prescribing Information](#) also is available.**

## ABOUT TOFIDENCE

# Making the move to a biosimilar: Learn more about TOFIDENCE

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TOFIDENCE is a biosimilar to ACTEMRA (tocilizumab), meaning it is an FDA-approved treatment that is as safe and effective as the original biologic. Like ACTEMRA, TOFIDENCE is an interleukin-6 (IL-6) receptor inhibitor that works to reduce inflammation in your body and, as a result, may help reduce joint pain and swelling from arthritis.

	ACTEMRA	TOFIDENCE
Approved uses in rheumatoid arthritis (RA), giant cell arteritis (GCA), systemic juvenile idiopathic arthritis (SJIA), polyarticular juvenile idiopathic arthritis (PJIA), and COVID-19*	✓	✓
Given the same way (in IV form) <sup>†</sup>	✓	✓
Works the same way in your body	✓	✓
Same treatment benefits	✓	✓
Same potential side effects	✓	✓

\*TOFIDENCE is not approved for the following indications: systemic sclerosis-associated interstitial lung disease (SSc-ILD) and cytokine release syndrome (CRS).  
<sup>†</sup>ACTEMRA is also available in a subcutaneous (under the skin) formulation.

FDA, US Food and Drug Administration.

Please see Important Safety Information on pages 1-5.

## ABOUT BIOSIMILARS

# A biosimilar works in your body the same way as the biologic it's based on, offering the same treatment benefits and potential side effects

### A biosimilar is an FDA-approved medicine that is:

- Highly similar to the original biologic medicine it is based on
- As safe and effective as the original biologic
- Biosimilars may also be available at a lower cost than the original biologic\*

\*Cost and coverage for specific biosimilars are dependent on the terms and conditions of your individual insurance benefits, including any applicable deductible, co-insurance, or co-payment.



## DOSING AND ADMINISTRATION

### Preparing for an infusion

A little preparation can go a long way in making your infusion experience as comfortable as possible

Here are a few tips to keep in mind:



#### Confirm the logistics

- Double-check your appointment time, date, and location
- Arrange for a ride to and from your appointment if needed



#### Dress comfortably

- Wear loose-fitting clothes with sleeves that roll up easily to allow access to your arms
- Treatment centers can be chilly, so bring a cozy layer like a hoodie or blanket, just in case



#### Pack a “comfort kit”

- Include headphones, music, podcasts, or a good book to pass time during the infusion
- Bring snacks and water
- Don’t forget chargers for your devices, or other personal items like lip balm and hand sanitizer



#### Eat beforehand

A light, healthy meal can help you feel your best during the infusion, especially if you’re prone to nausea or lightheadedness



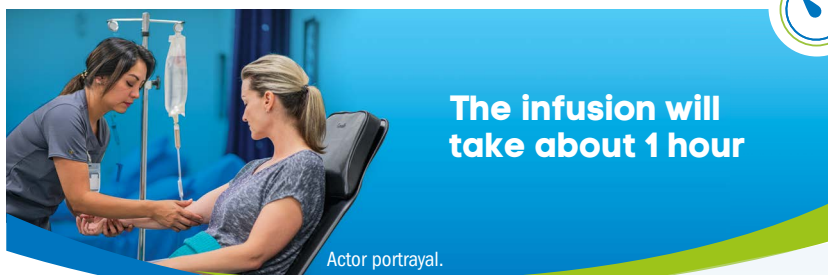
#### Hydrate

Good hydration can make it easier to access veins for your IV and may help you feel better during the infusion process

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## What to expect on infusion day

You can expect to receive TOFIDENCE (tocilizumab-bavi) as an IV infusion (a needle placed in a vein in your arm)



Actor portrayal.

For rheumatoid arthritis (RA), giant cell arteritis (GCA), or polyarticular juvenile idiopathic arthritis (PJIA)

**1 dose every 4 weeks**

For systemic juvenile idiopathic arthritis (SJIA)

**1 dose every 2 weeks**

For COVID-19

**A single dose**

With one additional dose if needed

### Your health care provider will weigh you before your infusion

Your TOFIDENCE dose is based on your weight, so you can expect to be weighed at your infusion appointment. If your weight changes, your health care provider may decide to adjust your dose.



**Keep all of your follow-up infusion appointments and get your blood tests as instructed by your health care provider**

While taking TOFIDENCE, **you may continue to use other medicines that help treat your RA, PJIA, SJIA, or COVID-19**, such as methotrexate (MTX), non-steroidal anti-inflammatory drugs (NSAIDs), and prescription steroids, as instructed by your health care provider.

## THE ORGANON ACCESS PROGRAM

# Learn about access support for TOFIDENCE

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The Organon Access Program is here to help you understand your insurance coverage and make TOFIDENCE more affordable for eligible patients



To speak with a representative from The Organon Access Program for TOFIDENCE, call **1-855-635-9581**, 8:00 AM to 8:00 PM ET, Monday through Friday, or learn more at [organonaccessprogram-tofidence.com/hcc](https://organonaccessprogram-tofidence.com/hcc)



### Insurance and coverage support

We can work with your insurance company to find out if TOFIDENCE is covered, what your out-of-pocket costs might be (like your deductible or co-pay), and whether your plan requires any special steps—like getting approval before starting treatment.



### Co-pay savings for eligible patients\*

Our co-pay assistance has been developed to address the costs you may incur during your treatment journey. Once enrolled, eligible, privately insured patients could pay as little as \$0 of their co-pay per infusion.

\*Not all patients are eligible to use the co-pay savings card. Certain restrictions apply.

The Organon Patient Assistance Program is also available and may provide certain Organon medicines at no cost to eligible patients. This program is separate from The Organon Access Program and has different eligibility criteria. Please visit [organonhelps.com/TOFIDENCE](https://organonhelps.com/TOFIDENCE) for more specific information on eligibility and benefits of the Organon Patient Assistance Program.



See if you are eligible for out-of-pocket cost assistance from Organon at [organonaccessprogram-tofidence.com/hcc](https://organonaccessprogram-tofidence.com/hcc)

ORGANON BIOSIMILARS

# TOFIDENCE (tocilizumab-bavi) is brought to you by Organon Biosimilars

We are an experienced biosimilar company with:

**8+** years dedicated to biosimilars in the US

**6** biosimilars approved in the US and still counting

**5** therapeutic areas treated across the Organon Biosimilars portfolio:



Cancer care



Gut conditions



Skin conditions



Joint conditions



Bone health



*Dare to move forward.  
Our commitment is all in.*

We are committed to creating a sustainable health care future through development of accessible and effective treatment options for patients

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TOFIDENCE is  
a biosimilar  
to ACTEMRA  
(tocilizumab)



TOFIDENCE and  
ACTEMRA work  
the same way in  
your body



Access support  
is available for  
eligible patients

Learn more about treatment  
at [TOFIDENCE.com](https://www.tofidence.com)

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