

Medication Guide
TOFIDENCE™ (TOE-FIH-DENCE)
(tocilizumab-bavi) injection
for intravenous use

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

TOFIDENCE can cause serious side effects including:

- 1. 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).

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.

Before starting TOFIDENCE, tell your healthcare provider if you:

- think you have an infection or have symptoms of an infection, with or without a fever, such as:
 - sweating or chills
 - shortness of breath
 - warm, red, or painful skin or sores on your body
 - feel very tired
 - muscle aches
 - blood in phlegm
 - diarrhea or stomach pain
 - cough
 - weight loss
 - burning when you urinate or urinating more often than normal
- are being treated for an infection.
- get a lot of infections or have infections that keep coming back.
- have diabetes, HIV, or a weak immune system. People with these conditions have a higher chance for infections.
- have TB, or have been in close contact with someone with TB.
- live or have lived, 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 (histoplasmosis, coccidiomycosis, or blastomycosis). These infections may happen or become more severe if you use TOFIDENCE. Ask your healthcare provider, if you do not know if you have lived in an area where these infections are common.
- have or have had hepatitis B.

After starting TOFIDENCE, call your healthcare provider right away if you have any symptoms of an infection. TOFIDENCE can make you more likely to get infections or make worse any infection that you have.

2. Tears (perforation) of the stomach or intestines.

- Tell 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.

3. 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
- weakness
- nausea and vomiting
- confusion
- dark “tea-colored” urine

of your stomach-area

- light colored stools

4. Changes in certain laboratory test results. Your healthcare provider should do blood tests before you start receiving TOFIDENCE. 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. You may also have changes in other laboratory tests, such as your blood cholesterol levels. Your healthcare provider should do blood tests to check your cholesterol levels 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.

Your healthcare provider may stop your TOFIDENCE treatment for a period of time or change your dose of medicine if needed because of changes in these blood test results.

5. 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.

See **“What are the possible side effects with TOFIDENCE?”** for more information about side effects.

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 PJIA ages 2 and above.
- To treat people with active 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.

Do not take TOFIDENCE: if you are allergic to tocilizumab products, or any of the ingredients in TOFIDENCE. See the end of this Medication Guide for a complete list of ingredients in TOFIDENCE.

Before you receive TOFIDENCE, tell your healthcare provider about all of your medical conditions, including if you:

- have an infection. See **“What is the most important information I should know about TOFIDENCE?”**
- have liver problems.
- have any stomach-area (abdominal) pain or been diagnosed with diverticulitis or ulcers in your stomach or intestines.
- have had a reaction to tocilizumab products or any of the ingredients in TOFIDENCE before.
- have or had a condition that affects your nervous system, such as multiple sclerosis.
- have recently received or are scheduled to receive a vaccine:
 - All vaccines should be brought up-to-date before starting TOFIDENCE, unless urgent treatment initiation is required.
 - People who take TOFIDENCE should not receive live vaccines.
 - People taking TOFIDENCE can receive non-live vaccines.
- plan to have surgery or a medical procedure.
- are pregnant or plan to become pregnant. TOFIDENCE may harm your unborn baby. Tell your healthcare provider if you become pregnant or think you may be pregnant during treatment with TOFIDENCE.
- are breastfeeding or plan to breastfeed. It is not known if TOFIDENCE passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take TOFIDENCE.

Tell your healthcare provider about all of the medicines you take, including prescription, over-the-counter medicines, vitamins and herbal supplements. TOFIDENCE and other medicines may affect each other causing side effects.

Especially tell your healthcare provider if you take:

- any other medicines to treat your RA. Taking TOFIDENCE with these medicines may increase your risk of infection.
- medicines that affect the way certain liver enzymes work. Ask your healthcare provider if you are not sure if your medicine is one of these.

Know the medicines you take. Keep a list of them to show to your healthcare provider and pharmacist when you get a new medicine.

How will I receive TOFIDENCE?

Into a vein (IV or intravenous infusion) for Rheumatoid Arthritis, Giant Cell Arteritis, PJIA, SJIA, or COVID-19:

- If your healthcare provider prescribes TOFIDENCE as an IV infusion, you will receive TOFIDENCE from a healthcare provider through a needle placed in a vein in your arm. The infusion will take about 1 hour to give you the full dose of medicine.
- For rheumatoid arthritis, giant cell arteritis or PJIA you will receive a dose of TOFIDENCE about every 4 weeks.
- For SJIA you will receive a dose of TOFIDENCE about every 2 weeks.
- For COVID-19, you will receive a single dose of TOFIDENCE, and if needed one additional dose.
- While taking TOFIDENCE, you may continue to use other medicines that help treat your rheumatoid arthritis, PJIA, SJIA, or COVID-19 such as methotrexate, non-steroidal anti-inflammatory drugs (NSAIDs) and prescription steroids, as instructed by your healthcare provider.
- Keep all of your follow-up appointments and get your blood tests as ordered by your healthcare provider.

What are the possible side effects with TOFIDENCE?

TOFIDENCE can cause serious side effects, including:

- See **“What is the most important information I should know about TOFIDENCE?”**
- **Hepatitis B infection** in people who carry the virus in their blood. 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 of a possible hepatitis B infection:
 - 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
- **Serious Allergic Reactions.** Serious allergic reactions, including death, can happen with TOFIDENCE. 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:
 - swelling of your face, lips, mouth, or tongue
 - trouble breathing
 - 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.

The most common side effects of TOFIDENCE include:

- upper respiratory tract infections (common cold, sinus infections)
- headache
- 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. For more information, ask your healthcare provider or pharmacist.

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 Biogen MA Inc. at 1-877-422-8360. .

General information about the safe and effective use of TOFIDENCE.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not give TOFIDENCE to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about TOFIDENCE that is written for health professionals.

What are the ingredients in TOFIDENCE?

Active ingredient: tocilizumab-bavi.

Inactive ingredients of Intravenous TOFIDENCE: arginine hydrochloride, histidine, L-histidine hydrochloride monohydrate, polysorbate 80, sucrose, and water for Injection.

TOFIDENCE is a trademark of Biogen MA Inc.

Manufactured by: Biogen MA Inc., Cambridge, MA 02142, U.S. License No.: 2344

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For more information, go to www.tofidence.com or call 1-877-422-8360 .

Medication Guide has been approved by the U.S. Food and Drug Administration

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