Tofidence™
(tocilizumab-bavi)
injection, for intravenous use

ORGANON Biosimilars | *Dare to move forward.* ***Our commitment is all in.***

TOFIDENCE (tocilizumab-bavi) injection, for intravenous use, a biosimilar to ACTEMRA (tocilizumab), available in the same IV product presentations and dosing strengths currently administered by health care professionals*

*TOFIDENCE is not available for subcutaneous injection.

National Drug Codes (NDC) for TOFIDENCE

Code	Description
10-digit code: 64406-024-01 / 11-digit code: 64406-0024-01**	80 mg/4 mL single-dose vial
10-digit code: 64406-022-01 / 11-digit code: 64406-0022-01**	200 mg/10 mL single-dose vial
10-digit code: 64406-023-01 / 11-digit code: 64406-0023-01**	400 mg/20 mL single-dose vial

**Please note that although the FDA uses a 10-digit format when registering NDCs, payers often require an 11-digit NDC format on claim forms for billing purposes. The 10-digit TOFIDENCE format is converted to an 11-digit code by adding a zero (0) in front of the second group of numbers, eg, 64406-0024-01. It is important to communicate with your payers to determine the appropriate NDC format requirements.

To learn more about The Organon Access Program for TOFIDENCE, visit https://www.organonaccessprogram-tofidence.com/.

SELECTED SAFETY INFORMATION

RISK OF SERIOUS INFECTIONS

Patients treated with tocilizumab products, including TOFIDENCE, are at increased risk for developing serious infections that may lead to hospitalization or death, including tuberculosis (TB), bacterial, invasive fungal, viral, or other opportunistic infections. If a serious infection develops, interrupt TOFIDENCE until the infection is controlled.

Reported infections include:

- **Active tuberculosis, which may present with pulmonary or extrapulmonary disease. Patients, except those with COVID-19, should be tested for latent tuberculosis before TOFIDENCE use and during therapy. Treatment for latent infection should be initiated prior to TOFIDENCE use.**
- **Invasive fungal infections, including candidiasis, aspergillosis, and pneumocystis. Patients with invasive fungal infections may present with disseminated, rather than localized, disease.**
- **Bacterial, viral, and other infections due to opportunistic pathogens.**

Do not administer TOFIDENCE in patients with an active infection, including localized infections. The risks and benefits of treatment with TOFIDENCE should be carefully considered prior to initiating therapy in patients:

- with chronic or recurrent infection;
- who have been exposed to tuberculosis;
- with a history of serious or an opportunistic infection;
- who have resided or traveled in areas of endemic tuberculosis or endemic mycoses; or
- with underlying conditions that may predispose them to infection.

Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with TOFIDENCE, including the possible development of tuberculosis in patients who tested negative for latent tuberculosis infection prior to initiating therapy.

Hold TOFIDENCE if a patient develops a serious infection, an opportunistic infection, or sepsis. A patient who develops a new infection during treatment with TOFIDENCE should undergo a prompt and complete diagnostic workup appropriate for an immunocompromised patient, initiate appropriate antimicrobial therapy, and closely monitor the patient.

COVID-19

In patients with COVID-19, monitor for signs and symptoms of new infections during and after treatment with TOFIDENCE.

Tuberculosis

Evaluate patients for tuberculosis risk factors and test for latent infection prior to initiating TOFIDENCE.

Consider anti-tuberculosis therapy prior to initiation of TOFIDENCE in patients with a history of latent or active tuberculosis in whom an adequate course of treatment cannot be confirmed, and for patients with a negative test for latent tuberculosis but having risk factors for tuberculosis infection.

Closely monitor patients for the development of signs and symptoms of tuberculosis including patients who tested negative for latent tuberculosis infection prior to initiating therapy.

Patients with latent tuberculosis should be treated with standard antimycobacterial therapy before initiating TOFIDENCE.

Viral Reactivation

Viral reactivation has been reported with immunosuppressive biologic therapies and cases of herpes zoster exacerbation were observed in clinical studies with tocilizumab.

CONTRAINDICATIONS

TOFIDENCE is contraindicated in patients with known hypersensitivity to tocilizumab products.

WARNINGS AND PRECAUTIONS

GASTROINTESTINAL PERFORATIONS

Use TOFIDENCE with caution in patients who may be at increased risk for gastrointestinal perforation. Promptly evaluate patients presenting with fever, new onset abdominal symptoms, and change in bowel habits for early identification of gastrointestinal perforation.

HEPATOTOXICITY

Serious cases of hepatic injury have been observed in patients taking intravenous tocilizumab products. Some of these cases have resulted in liver transplant or death.

For RA and GCA patients, obtain a liver test panel (serum alanine aminotransferase [ALT], aspartate aminotransferase [AST], alkaline phosphatase, and total bilirubin) before initiating TOFIDENCE routinely. It is not recommended to initiate TOFIDENCE treatment in RA and GCA patients with elevated transaminases, ALT or AST greater than 1.5 x ULN. In patients who develop elevated ALT or AST greater than 5 x ULN, discontinue TOFIDENCE.

It is not recommended to initiate TOFIDENCE treatment in COVID-19 patients with elevated ALT or AST above 10 x ULN. Monitor ALT and AST during treatment.

Measure liver tests promptly in patients who report symptoms that may indicate liver injury, such as fatigue, anorexia, right upper abdominal discomfort, dark urine, or jaundice. If the patient is found to have abnormal liver tests, TOFIDENCE treatment should be interrupted and investigation done to establish the probable cause. TOFIDENCE should only be restarted in patients with another explanation for the liver test abnormalities after normalization of the liver tests.

A similar pattern of liver enzyme elevation is noted with tocilizumab products treatment in the PJIA and SJIA populations. Monitor liver test panel at the time of the second administration and thereafter every 4 to 8 weeks for PJIA and every 2 to 4 weeks for SJIA.

CHANGES IN LABORATORY PARAMETERS

Patients with RA, GCA, and COVID-19:

Neutropenia

Treatment with tocilizumab products was associated with a higher incidence of neutropenia.

It is not recommended to initiate TOFIDENCE treatment in RA and GCA patients with a low neutrophil count, i.e., absolute neutrophil count (ANC) less than 2000 per mm^3. In patients who develop an absolute neutrophil count less than 500 per mm^3, treatment is not recommended. It is not recommended to initiate TOFIDENCE treatment in COVID-19 patients with an ANC less than 1000 per mm^3. Neutrophils should be monitored.

Monitor neutrophils 4 to 8 weeks after start of therapy and every 3 months thereafter.

Thrombocytopenia

Treatment with tocilizumab products was associated with a reduction in platelet counts.

It is not recommended to initiate TOFIDENCE treatment in RA and GCA patients with a platelet count below 100,000 per mm^3. In patients who develop a platelet count less

Please read the next page for additional Selected Safety Information.

Administration Codes for TOFIDENCE

Type	Code	Description
CPT	96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
	96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug

HCPCS II Codes for TOFIDENCE

Coding System	Code	Description
HCPCS II	Q5133	Injection, tocilizumab-bavi (TOFIDENCE), biosimilar, 1 mg

Diagnosis Codes:
The codes above may be relevant when submitting a claim for TOFIDENCE. Please consult with the applicable payer to understand the payer's specific billing requirements. Health care professionals are solely responsible for selecting codes that appropriately reflect the patient's diagnosis, the services rendered, and the applicable payer's guidelines. Included are lists of codes that may be relevant for TOFIDENCE and its administration. This information is current as of June 2025. The information provided here is compiled from sources believed to be accurate, but Organon makes no representation that it is accurate.
CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System.

SELECTED SAFETY INFORMATION (continued)

than 50,000 per mm^3, treatment is not recommended.

Monitor platelets 4 to 8 weeks after start of therapy and every 3 months thereafter.

In COVID-19 patients with a platelet count less than 50,000 per mm^3, treatment is not recommended.

Elevated Liver Enzymes

Refer to Hepatotoxicity. (See above.)

Lipid Abnormalities

Treatment with tocilizumab products was associated with increases in lipid parameters such as total cholesterol, triglycerides, LDL cholesterol, and/or HDL cholesterol.

Assess lipid parameters approximately 4 to 8 weeks following initiation of TOFIDENCE therapy.

Patients with Polyarticular and Systemic Juvenile Idiopathic Arthritis:

A similar pattern of liver enzyme elevation, low neutrophil count, low platelet count, and lipid elevations is noted with tocilizumab products treatment in the PJIA and SJIA populations. Monitor neutrophils, platelets, ALT, and AST at the time of the second administration and thereafter every 4 to 8 weeks for PJIA and every 2 to 4 weeks for SJIA. Monitor lipids as above for approved adult indications.

IMMUNOSUPPRESSION

TOFIDENCE is an immunosuppressant, and treatment with immunosuppressants may result in an increased risk of malignancies.

HYPERSENSITIVITY REACTIONS, INCLUDING ANAPHYLAXIS

Hypersensitivity reactions, including anaphylaxis, have been reported in association with tocilizumab products and anaphylactic events with a fatal outcome have been reported with intravenous infusion of tocilizumab products. Reactions that required treatment discontinuation included generalized erythema, rash, and urticaria.

TOFIDENCE for intravenous use should only be infused by a healthcare professional with appropriate medical support to manage anaphylaxis. If a hypersensitivity reaction occurs, immediately discontinue TOFIDENCE; treat promptly, and monitor until signs and symptoms resolve.

DEMYELINATING DISORDERS

Prescribers should exercise caution in considering the use of TOFIDENCE in patients with preexisting or recent onset demyelinating disorders.

ACTIVE HEPATIC DISEASE AND HEPATIC IMPAIRMENT

Treatment with TOFIDENCE is not recommended in patients with active hepatic disease or hepatic impairment.

VACCINATIONS

Avoid use of live vaccines concurrently with TOFIDENCE as clinical safety has not been established.

No data are available on the effectiveness of vaccination in patients receiving tocilizumab products. Because IL-6 inhibition may interfere with the normal immune response to new antigens, it is recommended that all patients, particularly pediatric or elderly patients, if possible, be brought up to date with all immunizations in agreement with current immunization guidelines prior to initiating TOFIDENCE therapy.

ADVERSE REACTIONS

The most common adverse reactions (incidence of at least 5%) associated with tocilizumab-IV were upper respiratory tract infections, nasopharyngitis, headache, hypertension, and increased ALT.

DRUG INTERACTIONS

Cytochrome P450s in the liver are down-regulated by infection and inflammation stimuli including cytokines such as IL-6. Inhibition of IL-6 signaling in RA patients treated with tocilizumab products may restore CYP450 activities to higher levels than those in the absence of tocilizumab products leading to increased metabolism of drugs that are CYP450 substrates.

Exercise caution when coadministering TOFIDENCE with CYP3A4 substrate drugs where decrease in effectiveness is undesirable, e.g., oral contraceptives, lovastatin, atorvastatin, etc.

USE IN SPECIFIC POPULATIONS

Pregnancy

The available data with tocilizumab products from a pregnancy exposure registry, retrospective cohort study, pharmacovigilance, and published literature are insufficient to draw conclusions about a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. Based on the animal data, there may be a potential risk to the fetus.

Lactation

No information is available on the presence of tocilizumab products in human milk, the effects of the drug on the breastfed infant, or the effects of the drug on milk production. Discontinue drug or nursing, taking into consideration the importance of the drug to the mother.

INDICATIONS AND USAGE

Rheumatoid Arthritis (RA)

TOFIDENCE is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more Disease-Modifying Anti-Rheumatic Drugs (DMARDs).

Giant Cell Arteritis (GCA)

TOFIDENCE is indicated for the treatment of giant cell arteritis (GCA) in adult patients.

Polyarticular Juvenile Idiopathic Arthritis (PJIA)

TOFIDENCE is indicated for the treatment of active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older.

Systemic Juvenile Idiopathic Arthritis (SJIA)

TOFIDENCE is indicated for the treatment of active systemic juvenile idiopathic arthritis in patients 2 years of age and older.

Coronavirus Disease 2019 (COVID-19)

TOFIDENCE is indicated for the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adult patients who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).

Before prescribing TOFIDENCE, please read the accompanying Prescribing Information, including the Boxed Warning about serious infections. The Medication Guide also is available.
For additional copies of the Prescribing Information, please call 844-674-3200, visit TOFIDENCEPro.com, or contact your Organon representative.

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