Margenza®
(margetuximab-cmkb)
250 mg/10 mL injection for intravenous use

PRODUCT FACT SHEET

Company Name	MacroGenics, Inc.
Brand Name and Scientific Name	MARGENZA® (margetuximab-cmkb)
Indication[1]	MARGENZA is a HER2/neu receptor antagonist indicated, in combination with chemotherapy, for the treatment of adult patients with metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease. HER2-positive = human epidermal growth factor receptor 2 positive
How Supplied[1]	 MARGENZA injection is a clear to slightly opalescent, colorless to pale yellow or pale brown solution in a single-dose vial.
Packaging and National Drug Codes[1,2]	 Carton containing 1 vial (25 mg/mL) 10-digit NDC: 74527-022-02 11-digit NDC: 74527-0022-02  Carton containing 4 vials (25 mg/mL) 10-digit NDC: 74527-022-03 11-digit NDC: 74527-0022-03
Storage Requirements[1]	Store vials refrigerated at 2°C to 8°C (36°F to 46°F) in original carton to protect from light until time of use. **Do not freeze. Do not shake.**
Dosage and Administration[1]	• The recommended dose of MARGENZA is 15 mg/kg, administered as an intravenous infusion every 3 weeks (21-day cycle) until disease progression or unacceptable toxicity. • Administer MARGENZA as an intravenous infusion at 15 mg/kg over 120 minutes for the initial dose, then over a minimum of 30 minutes every 3 weeks for all subsequent doses. • On days when both MARGENZA and chemotherapy are to be administered, MARGENZA may be administered immediately after chemotherapy completion. • Refer to the respective Prescribing Information for each therapeutic agent administered in combination with MARGENZA for the recommended dosage information, as appropriate.

Financial assistance is available for eligible patients. To learn more, please call MARGENZA Access Support at 1-844-MED-MGNX (1-844-633-6469), Monday-Friday, 9 AM to 7 PM ET or visit www.MARGENZAsupport.com

CLICK HERE to download the MARGENZA Coding and Billing Guide

IMPORTANT SAFETY INFORMATION

WARNING: LEFT VENTRICULAR DYSFUNCTION AND EMBRYO-FETAL TOXICITY

- **Left Ventricular Dysfunction:** MARGENZA may lead to reductions in left ventricular ejection fraction (LVEF). Evaluate cardiac function prior to and during treatment. Discontinue MARGENZA treatment for a confirmed clinically significant decrease in left ventricular function.
- **Embryo-Fetal Toxicity:** Exposure to MARGENZA during pregnancy can cause embryo-fetal harm. Advise patients of the risk and need for effective contraception.

Please see additional Important Safety Information on the next page, and full Prescribing Information, including Boxed Warning.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNING & PRECAUTIONS:

Left Ventricular Dysfunction

- Left ventricular cardiac dysfunction can occur with MARGENZA.
- In SOPHIA, left ventricular dysfunction occurred in 1.9% of patients treated with MARGENZA.
- MARGENZA has not been studied in patients with a pretreatment LVEF value of <50%, a prior history of myocardial infarction or unstable angina within 6 months, or congestive heart failure NYHA class II-IV.
- Withhold MARGENZA for ≥16% absolute decrease in LVEF from pretreatment values or LVEF below institutional limits of normal (or 50% if no limits available) and ≥10% absolute decrease in LVEF from pretreatment values.
- Permanently discontinue MARGENZA if LVEF decline persists greater than 8 weeks, or dosing is interrupted more than 3 times due to LVEF decline.
- Evaluate cardiac function within 4 weeks prior to and every 3 months during and upon completion of treatment. Conduct thorough cardiac assessment, including history, physical examination, and determination of LVEF by echocardiogram or MUGA scan.
- Monitor cardiac function every 4 weeks if MARGENZA is withheld for significant left ventricular cardiac dysfunction.

Embryo-Fetal Toxicity

- Based on findings in animals and mechanism of action, MARGENZA can cause fetal harm when administered to a pregnant woman. Post-marketing studies of other HER2 directed antibodies during pregnancy resulted in cases of oligohydramnios and oligohydramnios sequence manifesting as pulmonary hypoplasia, skeletal abnormalities, and neonatal death.
- Verify pregnancy status of women of reproductive potential prior to initiation of MARGENZA.
- Advise pregnant women and women of reproductive potential that exposure to MARGENZA during pregnancy or within 4 months prior to conception can result in fetal harm.
- Advise women of reproductive potential to use effective contraception during treatment and for 4 months following the last dose of MARGENZA.

Infusion-Related Reactions (IRRs)

- MARGENZA can cause IRRs. Symptoms may include fever, chills, arthralgia, cough, dizziness, fatigue, nausea, vomiting, headache, diaphoresis, tachycardia, hypotension, pruritus, rash, urticaria, and dyspnea.
- In SOPHIA, IRRs were reported by 13% of patients on MARGENZA plus chemotherapy. Most of the IRRs occur during Cycle 1. Grade 3 IRRs were reported in 1.5% of MARGENZA-treated patients.
- Monitor patients during and after MARGENZA infusion. Have medications and emergency equipment to treat IRRs available for immediate use.
- In patients experiencing mild or moderate IRRs, decrease rate of infusion and consider premedications, including antihistamines, corticosteroids, and antipyretics. Monitor patients until symptoms completely resolve.
- Interrupt MARGENZA infusion in patients experiencing dyspnea or clinically significant hypotension and intervene with supportive medical therapy as needed. Permanently discontinue MARGENZA in all patients with severe or life-threatening IRRs.

MOST COMMON ADVERSE REACTIONS:

The most common adverse drug reactions (>10%) with MARGENZA in combination with chemotherapy are fatigue/asthenia (57%), nausea (33%), diarrhea (25%), vomiting (21%), constipation (19%), headache (19%), pyrexia (19%), alopecia (18%), abdominal pain (17%), peripheral neuropathy (16%), arthralgia/myalgia (14%), cough (14%), decreased appetite (14%), dyspnea (13%), infusion-related reactions (13%), palmar-plantar erythrodysesthesia (13%), and extremity pain (11%).

You may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch or to MacroGenics at (844)-MED-MGNX (844-633-6469).

Please see full Prescribing Information, including Boxed Warning.

References: 1. MARGENZA Prescribing Information. MacroGenics, Inc; 2020. **2.** Federal Register. Future Format of the National Drug Code; Public Hearing; Request for Comments. Vol 83, No. 152. Published August 7, 2018. Accessed January 26, 2022. https://www.federalregister.gov/documents/2018/08/07/2018-16807/future-format-of-the-national-drug-code-public-hearing-request-for-comments.

MACROGENICS®

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250 mg/10 mL Injection for Intravenous use