When treating relapsing forms of MS, go Glatopa®

Available in 2 dosage strengths[1]: 3-times-a-week 40 mg/mL • Once-daily 20 mg/mL

Glatopa is the first FDA-approved, substitutable generic for Copaxone® (glatiramer acetate injection) for the treatment of patients with relapsing forms of multiple sclerosis.[1-3]

The medication your patients expect and the support they deserve[1,3-6]

	Glatopa® (glatiramer acetate injection)	Copaxone® (glatiramer acetate injection)
Glatiramer acetate[3]	✓	✓
Therapeutically equivalent[3]	✓	✓
Patient Support Services Center[4,5]	✓	✓
Co-Pay Savings Program[4,5]	✓	✓
Injection device[1,6]	✓	✓
Once-daily dosing (20 mg/mL)[1,6]	✓	✓
3-times-a-week dosing (40 mg/mL)[1,6]	✓	✓

- Equivalent gene expression profiles between Glatopa and Copaxone® further confirm therapeutic equivalence[7]

Indication

Glatopa® (glatiramer acetate injection) is a prescription medicine used to treat relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

Important Safety Information

Glatopa® is contraindicated in patients with known hypersensitivity to glatiramer acetate or mannitol.

Approximately 16% of glatiramer acetate injection 20 mg/mL patients vs 4% of those on placebo, and approximately 2% of glatiramer acetate injection 40 mg/mL patients vs none on placebo experienced a constellation of symptoms that may occur immediately (within seconds to minutes, with the majority of symptoms observed within 1 hour) after injection and included at least 2 of the following: flushing, chest pain, palpitations, tachycardia, anxiety, dyspnea, throat constriction, and urticaria. These symptoms generally have their onset several months after the initiation of treatment, although they may occur earlier, and a given patient may experience 1 or several episodes of these symptoms. Typically, the symptoms were transient and self-limited and did not require treatment; however, there have been reports of patients with similar symptoms who received emergency medical care.

Transient chest pain was noted in 13% of glatiramer acetate injection 20 mg/mL patients vs 6% of placebo patients and approximately 2% of glatiramer acetate injection 40 mg/mL patients vs 1% on placebo. While some episodes of chest pain occurred in the context of the immediate post-injection reaction described above, many did not. The temporal relationship of this chest pain to an injection was not always known. The pain was transient, often unassociated with other symptoms, and appeared to have no clinical sequelae. Some patients experienced more than 1 such episode, and episodes usually began at least 1 month after the initiation of treatment.

At injection sites, localized lipoatrophy and, rarely, injection site skin necrosis may occur. Lipoatrophy may occur at various time after treatment onset (sometimes after several months) and is thought to be permanent. There is no known therapy for lipoatrophy.

Please see additional Important Safety Information on back and enclosed full Prescribing Information for Glatopa.

Glatopa®
(glatiramer acetate injection)
20mg/mL • 40mg/mL

GlatopaCare®

Rethink Generic. Go Glatopa®

Free, individualized support services for eligible patients, including 24/7 nurse support

Glatopa Co-Pay Program*

Eligible* patients may have a **$0 co-pay** per month for their Glatopa® (glatiramer acetate injection) 40 mg/mL or 20 mg/mL prescription. Your patients can ask their GlatopaCare Representative for details or call **1.855.GLATOPA (1.855.452.8672).**

Individualized injection support

Patients receive a free Glatopaject® device when they enroll in GlatopaCare. Nurse Trainers provide support, guidance, and 1-on-1 injection training in your patients' home or by phone.

Insurance and benefits information

GlatopaCare Representatives help patients understand their insurance benefits.

24/7 nurse support

GlatopaCare Nurses are available day or night to answer patients' questions related to Glatopa or to provide guidance on self-injection and proper injection technique.

***Glatopa Co-Pay Program Eligibility**

The Glatopa Co-Pay Program provides up to $9000 in annual co-pay support for Glatopa prescriptions. This program is not health insurance. This program is for insured patients only; uninsured cash-paying patients are not eligible. Patients are not eligible if prescriptions are paid, in whole or in part, by any state or federally funded programs, including but not limited to Medicare (including Part D, even in the coverage gap) or Medicaid, Medigap, VA, DOD, or TRICARE, or private indemnity, or HMO insurance plans that reimburse you for the entire cost of your prescription drugs, or where prohibited by law. Card may not be combined with any other rebate, coupon, or offer. Card has no cash value. Sandoz reserves the right to rescind, revoke, or amend this offer without further notice.

Important Safety Information (cont'd)

Because glatiramer acetate can modify immune response, it may interfere with immune functions. For example treatment with glatiramer acetate may interfere with recognition of foreign antigens in a way that would undermine the body's tumor surveillance and its defenses against infection. There is no evidence that glatiramer acetate does this, but there has not been a systematic evaluation of this risk.

Cases of hepatic injury, some severe, including liver failure and hepatitis with jaundice, have been reported with Glatopa. Hepatic injury has occurred from days to years after initiating treatment with Glatopa. If signs or symptoms of liver dysfunction occur, consider discontinuation of Glatopa.

The most common adverse reactions with glatiramer acetate injection 20 mg/mL vs placebo were injection site reactions (ISRs), such as erythema (43% vs 10%); vasodilatation (20% vs 5%); rash (19% vs 11%); dyspnea (14% vs 4%); and chest pain (13% vs 6%). The most common adverse reactions with glatiramer acetate injection 40 mg/mL vs placebo were ISRs, such as erythema (22% vs 2%).

ISRs were one of the most common adverse reactions leading to discontinuation of glatiramer acetate injection. ISRs, such as erythema, pain, pruritus, mass, edema, hypersensitivity, fibrosis and atrophy, occurred at a higher rate with glatiramer acetate than placebo.

To report SUSPECTED ADVERSE REACTIONS, contact Sandoz Inc. at 1-800-525-8747 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see enclosed full Prescribing Information for Glatopa.

References: 1. Glatopa Prescribing Information. Sandoz Inc. July 2020. **2.** FDA approves rst generic Copaxone to treat multiple sclerosis [press release]. US Food and Drug Administration; April 16, 2015. https://wayback.archive-it.org/7993/20171102214315/https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm443143.htm. Accessed March 11, 2020. **3.** US Department of Health and Human Services. *Approved Drug Products With Therapeutic Equivalence Evaluations: 41st Edition.* Washington, DC: US Department of Health and Human Services; 2021. **4.** GlatopaCare provides free individualized support to MS patients, families, and caregivers. Glatopa website. https://www.glatopa.com/glatopacare/what-is-glatopacare/. Accessed June 29, 2021. **5.** Here for Support. Copaxone website. https://www.copaxone.com/shared-solutions. Accessed June 29, 2021. **6.** Copaxone Prescribing Information. Teva Pharmaceuticals. July 2019. **7.** D'Alessandro JS, Duffner J, Pradines J, et al. Equivalent gene expression pro les between Glatopa™ and Copaxone®. *PLoS One.* 2015;10(10):e0140299. doi:10.1371/journal.pone.0140299.

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