This label may not be the latest approved by FDA.
For current labeling information, please visit https://www.fda.gov/drugsatfda

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use GLATOPA™ safely and effectively. See full prescribing information for GLATOPA™.

GLATOPA™ (glatiramer acetate injection), for subcutaneous use
Initial U.S. Approval: 1996

RECENT MAJOR CHANGES

Dosage and Administration, Recommended Dose (2.1)	03/2014
Dosage and Administration, Instructions for Use (2.2)	03/2014
Warnings and Precautions, Immediate Post-Injection Reaction (5.1)	01/2014
Warnings and Precautions, Chest Pain (5.2)	03/2014
Warnings and Precautions, Lipoatrophy and Skin Necrosis (5.3)	01/2014

INDICATIONS AND USAGE

Glatopa™ is not indicated for the treatment of patients with relapsing-remitting multiple sclerosis (1)

DOSAGE AND ADMINISTRATION

- For subcutaneous injection only. Glatopa 20 mg per mL does not need refrigeration when glatiramer acetate injection, USP (20 mg per mL, dosage 2)
- Glatopa™ 20 mg/mL per day (2.1)
- Do not use if solution is not clear or contains a precipitate (2.2)

DOSAGE FORMS AND STRENGTHS

- Injection: 20 mg/mL, single-use, ready-to-use syringe in a box of 30 (3)

CONTRAINDICATIONS

Known hypersensitivity to glatiramer acetate or mannitol (4)

WARNINGS AND PRECAUTIONS

- Immediate first-time administration of a dose of Glatopa 20 mg/mL may cause a transient chest discomfort and/or tightness, generally lasting minutes (5.1)
- Chest pain is common (Table 1 in 5.2)
- Lipoatrophy and/or necrosis may occur without proper injection technique and to a lesser extent with use (5.3)
- Glatopa can rarely cause anaphylaxis (5.4)

ADVERSE REACTIONS

- In a clinical study of glatiramer acetate injection 20 mg/mL, most common adverse reactions (≥10% and ≥1.5 times higher than placebo) were: flushing, chest pain, vasodilation, rash, dyspnea, and chest pain (6.1)

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.

USE IN SPECIFIC POPULATIONS

- Nursing Mothers: It is unknown if glatiramer acetate is excreted in human milk (8.3)
- Pediatric Use: Safety and effectiveness of Glatopa have not been established in patients under 18 years of age (8.4)

PATIENT COUNSELING INFORMATION

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 03/2014

FULL PRESCRIBING INFORMATION: CONTENTS*

1 INDICATIONS AND USAGE
2 DOSAGE AND ADMINISTRATION
2.1 Recommended Dose
2.2 Instructions for Use
3 DOSAGE FORMS AND STRENGTHS
4 CONTRAINDICATIONS
5 WARNINGS AND PRECAUTIONS
5.1 Immediate Post-Injection Reaction
5.2 Chest Pain
5.3 Lipoatrophy and Skin Necrosis
5.4 Potential Effects on Immune Response
6 ADVERSE REACTIONS
6.1 Clinical Trials Experience
6.2 Postmarketing Experience
7 DRUG INTERACTIONS
8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
8.2 Labor and Delivery
8.3 Nursing Mothers
8.4 Pediatric Use
8.5 Geriatric Use
8.6 Use in Patients with Impaired Renal Function
9 DESCRIPTION
10 CLINICAL PHARMACOLOGY
12.1 Mechanism of Action
12.2 Pharmacodynamics
12.3 Pharmacokinetics
13 NONCLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
14 CLINICAL STUDIES
16 HOW SUPPLIED/STORAGE AND HANDLING
17 PATIENT COUNSELING INFORMATION
PATIENT INFORMATION
Medication Guide

* Sections or subsections omitted from the full prescribing information are not listed

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Glatopa™ is not indicated for the treatment of patients with relapsing-remitting multiple sclerosis.

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dose

Glatopa, for subcutaneous injection only. Do not administer intravenously. The recommended dose is:

- Glatopa™ 20 mg per mL injection, 1 mL (20 mg) per mL, 1 mL subcutaneously

2.2 Instructions for Use

Remove one blister-packaged Glatopa syringe from the refrigerator. Let the pre-filled syringe reach room temperature (68-77 °F). Administer within 24 hours of removal from refrigerator. Do not use if solution is not clear or contains a precipitate. Do not shake or vigorously shake the syringe. Do not use if the syringe is damaged or if the seal or tip cap is missing or damaged. Do not use if the syringe is expired.

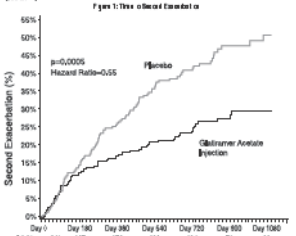
Use a fresh subcutaneous injection site for each administration. Do not inject into areas of skin that are tender, bruised, red, or hard. Do not inject into areas of skin with scars or stretch marks. Do not inject into areas of skin with moles or birthmarks. Do not inject into areas of skin with a tattoo. Do not inject into areas of skin with a rash or lesions. Do not inject into areas of skin with a vein or artery that can be seen or felt. Do not inject into areas of skin with a bony prominence.

Remove the syringe from the blister pack. Remove the tip cap from the syringe. Do not remove the plunger rod. Do not remove the needle shield. Do not remove the needle shield. Do not remove the needle shield

This label may not be the latest approved by FDA.
For current labeling information, please visit https://www.fda.gov/drugsatfda

(See bend)

Figure 1: Time to Second Exacerbation



Patients treated with glatiramer acetate, next confirmed to achieve new T2 lesions at the scheduled month 18 exam (0.16 versus 0.38 lesions; rate ratio 0.38 to 0.98; p<0.0005). Additionally, based on a mixed model for repeated measures analysis, patients treated with glatiramer acetate achieved a statistically significant reduction in the number of new T2 lesions (p<0.0001).

Study 4 was a multicenter, study, in which MRI parameters were used both as primary and secondary endpoints. A total of 239 patients with RRMS and at least one acute relapse in the previous 6 months were randomized to receive either placebo or glatiramer acetate 20 mg/mL subcutaneously once daily for 36 months. Patients were treated in double-blind, randomized fashion, using a computer-generated randomization schedule. Patients were treated in double-blind fashion with glatiramer acetate 20 mg/mL or placebo, administered subcutaneously once daily for 36 months