

GLATIRAMER ACETATE- glatiramer acetate injection, solution
Italfarmaco SpA

GLATIRAMER ACETATE injection, for subcutaneous use

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 11797-764-03

ONCE DAILY

**Glatiramer Acetate
Injection**

**20
mg/mL**

FOR SUBCUTANEOUS INJECTION ONLY

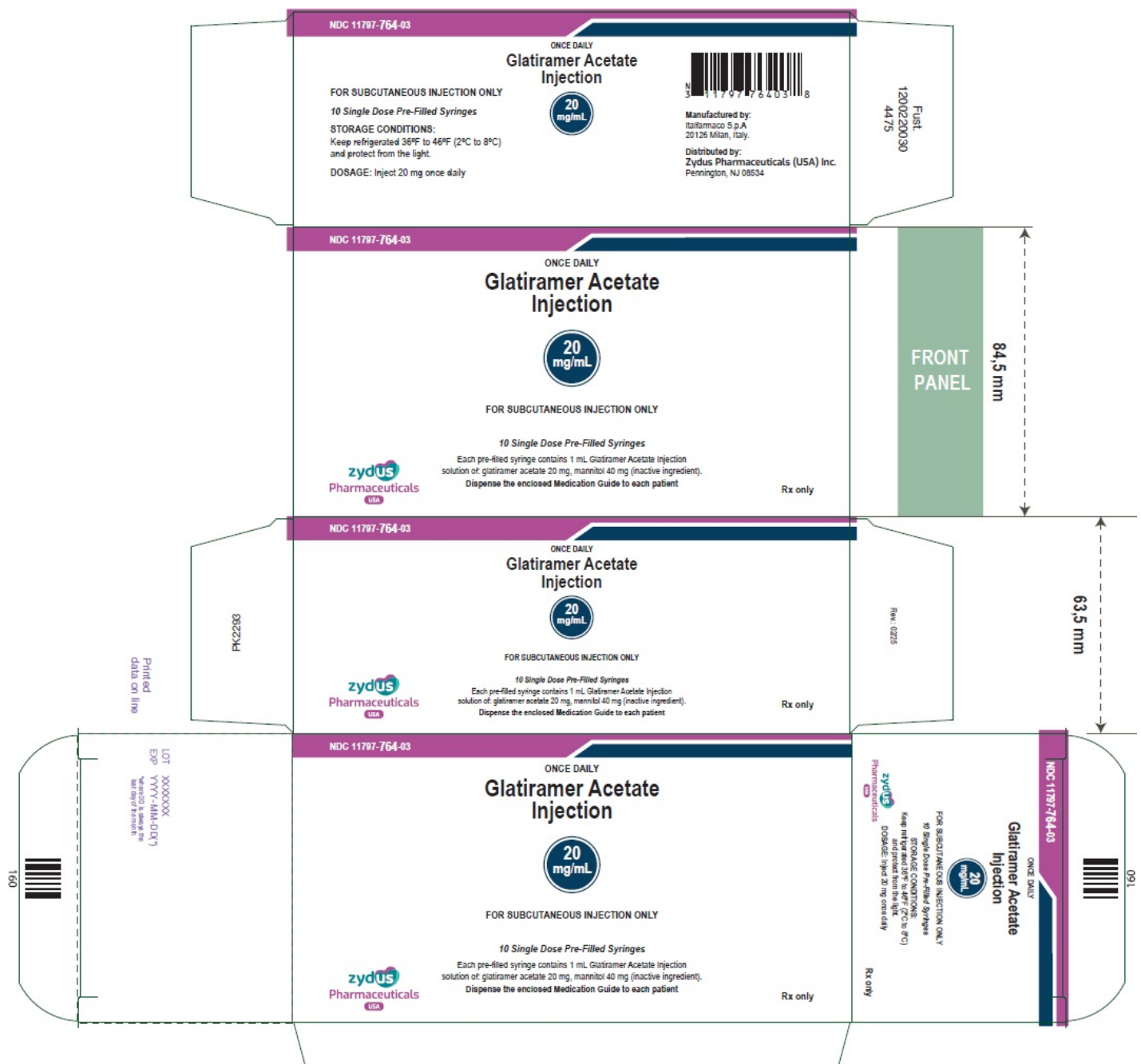
30 pre-filled syringe (3 carton box of 10 syringes)

Each pre-filled syringe contains 1 mL Glatiramer Acetate Injection solution of: glatiramer acetate 20 mg, mannitol 40 mg (inactive ingredient).

Dispense the enclosed Medication Guide to each patient

**zydus
Pharmaceuticals
USA**

Rx only



NDC 11797-765-03

THREE TIMES A WEEK

**Glatiramer Acetate
Injection**

**40
mg/mL**

FOR SUBCUTANEOUS INJECTION ONLY

12 Single Dose Pre-Filled Syringes

Each pre-filled syringe contains 1 mL Glatiramer Acetate Injection solution of: glatiramer acetate 40 mg, mannitol 40 mg (inactive ingredient).

GLATIRAMER ACETATE

glatiramer acetate injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:11797-764
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
GLATIRAMER ACETATE (UNII: 5M691HL4BO) (GLATIRAMER - UNII:U782C039QP)	GLATIRAMER ACETATE	20 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
MANNITOL (UNII: 3OWL53L36A)	40 mg in 1 mL
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11797-764-03	30 in 1 CARTON	11/10/2025	
1		1 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208468	11/10/2025	

GLATIRAMER ACETATE

glatiramer acetate injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:11797-765
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
GLATIRAMER ACETATE (UNII: 5M691HL4BO) (GLATIRAMER - UNII:U782C039QP)	GLATIRAMER ACETATE	40 mg in 1 mL

Inactive Ingredients				
Ingredient Name			Strength	
MANNITOL (UNII: 3OWL53L36A)			40 mg in 1 mL	
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11797-765-03	12 in 1 CARTON	11/10/2025	
1		1 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA		ANDA208468	11/10/2025	

Labeler - Italfarmaco SpA (428179329)

Establishment			
Name	Address	ID/FEI	Business Operations
Italfarmaco SpA		428179329	MANUFACTURE(11797-764, 11797-765) , ANALYSIS(11797-764, 11797-765) , PACK(11797-764, 11797-765)

Revised: 10/2025

Italfarmaco SpA