

FDA Home³ Drug Databases⁴ Orange Book⁵

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations Patent and Exclusivity Search Results from query on Appl No 020622 Product 003 in the OB_Rx list.

Patent Data

Appl No	Prod No	Patent No	Patent Expiration	Drug Substance Claim	Drug Product Claim	Patent Use Code	Delist Requested
N020622	003	8232250	Aug 19, 2030			U - 441	
N020622	003	8399413	Aug 19, 2030			U - 441	

Exclusivity Data

Appl No	Prod No	Exclusivity Code	Exclusivity Expiration
N020622	003	NP	Jan 28, 2017

Additional information:

- 1. Patents are published upon receipt by the Orange Book Staff and may not reflect the official receipt date as described in 21 CFR 314.53(d)(5).
- 2. Patents listed prior to August 18, 2003 are flagged with method of use claims only as applicable and submitted by the sponsor. These patents may not be flagged with respect to other claims which may apply.

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U.S. Department of Health & Human Services

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FDA Home³ Drug Databases⁴ Orange Book⁵ Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations Search results from the "OB_Rx" table for query on "020622."

Active Ingredient: GLATIRAMER ACETATE

Dosage Form; Route: INJECTABLE; SUBCUTANEOUS

Proprietary Name: COPAXONE

Applicant: TEVA PHARMS USA

Strength: 20MG/ML
Application Number: N020622
Product Number: 002

Approval Date: Feb 12, 2002

Reference Listed Drug Yes RX/OTC/DISCN: RX

TE Code:

Patent and Exclusivity Info for this product: View

Active Ingredient: GLATIRAMER ACETATE

Dosage Form; Route: INJECTABLE; SUBCUTANEOUS

Proprietary Name: COPAXONE

Applicant: TEVA PHARMS USA

Strength: 40MG/ML
Application Number: N020622
Product Number: 003

Approval Date: Jan 28, 2014

Reference Listed Drug Yes RX/OTC/DISCN: RX

TE Code:

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Office of Generic Drugs

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