Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

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Product Details for NDA 206276

PAZEO (OLOPATADINE HYDROCHLORIDE)
EQ 0.7% BASE Marketing Status: Prescription

Active Ingredient: OLOPATADINE HYDROCHLORIDE
Proprietary Name: PAZEO
Dosage Form; Route of Administration: SOLUTION/DROPS; OPHTHALMIC
Strength: EQ 0.7% BASE
Reference Listed Drug: Yes
Reference Standard: Yes
TE Code:
Application Number: N206276
Product Number: 001
Approval Date: Jan 30, 2015
Applicant Holder Full Name: NOVARTIS PHARMACEUTICALS CORP
Marketing Status: Prescription
Patent and Exclusivity Information (patent_info.cfm?Product_No=001&Appl_No=206276&Appl_type=N)

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Additional Information about Patents

- Patent information is published on or after the submission date as defined in 21 CFR 314.53 (d)(5).
- Patent listings published prior to August 18, 2003, only identify method-of-use claims. The listed patents may include drug substance and/or drug product claims that are not indicated in the listing.
- As of December 5, 2016, an NDA holder submitting information on a patent that claims both the drug substance and the drug product (and is eligible for listing on either basis) is required only to specify that it claims either the drug substance or the drug product. Orange Book users should not rely on an Orange Book patent listing, regardless of when first published, to determine the range of patent claims that may be asserted by an NDA holder or patent owner.

Patent and Exclusivity for: N206276

Product 001
OLOPATADINE HYDROCHLORIDE (PAZEO) SOLUTION/DROPS EQ 0.7% BASE

Patent Data

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested
001	8791154	05/19/2032		DP	U-1680	
001	9533053	05/19/2032		DP		

Exclusivity Data

Product No	Exclusivity Code	Exclusivity Expiration
001	NP	01/30/2018
001	NP *PED	07/30/2018

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View a list of all exclusivity codes (results_exclusivity.cfm)