Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Search Results for Proprietary Name, Active Ingredient or Application Number: *017821*

RX OTC DISCN

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Showing 1 to 2 of 2 entries

Search for text in the table

Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
DISCN	CYCLOBENZAPRINE HYDROCHLORIDE	FLEXERIL	N017821	TABLET	ORAL	5MG **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**		RLD		JANSSEN RESEARCH AND DEVELOPMENT LLC
DISCN	CYCLOBENZAPRINE HYDROCHLORIDE	FLEXERIL	N017821	TABLET	ORAL	10MG **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**		RLD		JANSSEN RESEARCH AND DEVELOPMENT LLC

Showing 1 to 2 of 2 entries

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Product Details for NDA 017821

Expand all

FLEXERIL (CYCLOBENZAPRINE HYDROCHLORIDE)
5MG **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**
Marketing Status: Discontinued

Active Ingredient: CYCLOBENZAPRINE HYDROCHLORIDE
Proprietary Name: FLEXERIL
Dosage Form; Route of Administration: TABLET; ORAL
Strength: 5MG **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**
Reference Listed Drug: Yes
Reference Standard: No
TE Code:
Application Number: N017821
Product Number: 001
Approval Date: Approved Prior to Jan 1, 1982
Applicant Holder Full Name: JANSSEN RESEARCH AND DEVELOPMENT LLC
Marketing Status: Discontinued
Patent and Exclusivity Information

FLEXERIL (CYCLOBENZAPRINE HYDROCHLORIDE)
10MG **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**
Marketing Status: Discontinued

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: N017821

Product 001
CYCLOBENZAPRINE HYDROCHLORIDE (FLEXERIL) TABLET 5MG **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**

Patent Data

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date
Your search did not return any results							

Exclusivity Data

Product No	Exclusivity Code	Exclusivity Expiration
Your search did not return any results		

Product Details for NDA 017821

Expand all

FLEXERIL (CYCLOBENZAPRINE HYDROCHLORIDE)
5MG **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**
Marketing Status: Discontinued

FLEXERIL (CYCLOBENZAPRINE HYDROCHLORIDE)
10MG **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**
Marketing Status: Discontinued

Active Ingredient: CYCLOBENZAPRINE HYDROCHLORIDE
Proprietary Name: FLEXERIL
Dosage Form; Route of Administration: TABLET; ORAL
Strength: 10MG **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**
Reference Listed Drug: Yes
Reference Standard: No
TE Code:
Application Number: N017821
Product Number: 002
Approval Date: Approved Prior to Jan 1, 1982
Applicant Holder Full Name: JANSSEN RESEARCH AND DEVELOPMENT LLC
Marketing Status: Discontinued
Patent and Exclusivity Information

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.
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Patent and Exclusivity for: N017821

Product 002
CYCLOBENZAPRINE HYDROCHLORIDE (FLEXERIL) TABLET 10MG **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**

Patent Data

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date
Your search did not return any results							

Exclusivity Data

Product No	Exclusivity Code	Exclusivity Expiration
Your search did not return any results		