Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

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

RX OTC DISCN

CSV | Excel | Print

Display 50 records per page

Showing 1 to 3 of 3 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	MIDODRINE HYDROCHLORIDE	PROAMATINE	N019815	TABLET	ORAL	2.5MG **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**		RLD		TAKEDA PHARMACEUTICALS USA INC
DISCN	MIDODRINE HYDROCHLORIDE	PROAMATINE	N019815	TABLET	ORAL	5MG **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**		RLD		TAKEDA PHARMACEUTICALS USA INC
DISCN	MIDODRINE HYDROCHLORIDE	PROAMATINE	N019815	TABLET	ORAL	10MG **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**		RLD		TAKEDA PHARMACEUTICALS USA INC

Showing 1 to 3 of 3 entries

Previous 1 Next

Product Details for NDA 019815

Expand all

PROAMATINE (MIDODRINE HYDROCHLORIDE)
2.5MG **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**
Marketing Status: Discontinued

Active Ingredient: MIDODRINE HYDROCHLORIDE
Proprietary Name: PROAMATINE
Dosage Form; Route of Administration: TABLET; ORAL
Strength: 2.5MG **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**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: N019815
Product Number: 001
Approval Date: Sep 6, 1996
Applicant Holder Full Name: TAKEDA PHARMACEUTICALS USA INC
Marketing Status: Discontinued
Patent and Exclusivity Information

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5MG **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**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

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10MG **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**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

Patent and Exclusivity for: N019815

Product 001
MIDODRINE HYDROCHLORIDE (PROAMATINE) TABLET 2.5MG **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**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 019815

Expand all

PROAMATINE (MIDODRINE HYDROCHLORIDE)
2.5MG **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**
Marketing Status: Discontinued

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

Active Ingredient: MIDODRINE HYDROCHLORIDE
Proprietary Name: PROAMATINE
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: N019815
Product Number: 002
Approval Date: Sep 6, 1996
Applicant Holder Full Name: TAKEDA PHARMACEUTICALS USA INC
Marketing Status: Discontinued
Patent and Exclusivity Information

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

Patent and Exclusivity for: N019815

Product 002
MIDODRINE HYDROCHLORIDE (PROAMATINE) 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 019815

Expand all

PROAMATINE (MIDODRINE HYDROCHLORIDE)
2.5MG **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**
Marketing Status: Discontinued

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

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

Active Ingredient: MIDODRINE HYDROCHLORIDE
Proprietary Name: PROAMATINE
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: N019815
Product Number: 003
Approval Date: Mar 20, 2002
Applicant Holder Full Name: TAKEDA PHARMACEUTICALS USA INC
Marketing Status: Discontinued
Patent and Exclusivity Information

Patent and Exclusivity for: N019815

Product 003
MIDODRINE HYDROCHLORIDE (PROAMATINE) 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		