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January 21, 2013

Food and Drug Administration
Division of Dockets Management (HFA-305)
Department of Health and Human Services
5360 Fishers Lane,
Room 1061
Rockville, MD 20852

AMENDMENT TO CITIZEN PETITION FDA-2013-P-0027/CP1
FOR MIDODRINE HYDROCHLORIDE TABLETS

Dear Sir or Madam,

We are hereby submitting replacement attachment for the attachments previously submitted with the original Citizen's Petition for Midodrine Hydrochloride Tablets submitted on December 28, 2012 and filed on December 31, 2012. We request that you replace these attachments with those previously submitted.

If you have any questions, please do not hesitate to contact me at the information in the signature line below.

Respectfully submitted,

Frederik Defesche
President
Tel: (760) 683-0901
Fax: (760) 301-0048
E-mail: fdefesche@custopharm.com

Attachments

U.S. Food & Drug Administration

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

- [1]

FDA Home[2]

Active Ingredient Search Results from "OB_Disc" table for query on "midodrine."

Appl No	Active Ingredient	Dosage Form; Route	Strength	Proprietary Name	Applicant
N019815	MIDODRINE HYDROCHLORIDE	TABLET; ORAL	10MG	PROAMATINE	SHIRE LLC
N019815	MIDODRINE HYDROCHLORIDE	TABLET; ORAL	2.5MG	PROAMATINE	SHIRE LLC
N019815	MIDODRINE HYDROCHLORIDE	TABLET; ORAL	5MG	PROAMATINE	SHIRE LLC

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FDA Home[2] Drug Databases[3] Orange Book[4]

Search results from the "OB_Disc" table for query on "019815."

Active Ingredient:	MIDODRINE HYDROCHLORIDE
Dosage Form;Route:	TABLET; ORAL
Proprietary Name:	PROAMATINE
Applicant:	SHIRE LLC
Strength:	2.5MG
Application Number:	N019815
Product Number:	001
Approval Date:	Sep 6, 1996
RX/OTC/DISCN:	DISCN
Patent and Exclusivity Info for this product:	View

Active Ingredient:	MIDODRINE HYDROCHLORIDE
Dosage Form;Route:	TABLET; ORAL
Proprietary Name:	PROAMATINE
Applicant:	SHIRE LLC
Strength:	5MG
Application Number:	N019815
Product Number:	002
Approval Date:	Sep 6, 1996
RX/OTC/DISCN:	DISCN
Patent and Exclusivity Info for this product:	View

Active Ingredient:	MIDODRINE HYDROCHLORIDE
Dosage Form;Route:	TABLET; ORAL
Proprietary Name:	PROAMATINE
Applicant:	SHIRE LLC
Strength:	10MG
Application Number:	N019815
Product Number:	003
Approval Date:	Mar 20, 2002
RX/OTC/DISCN:	DISCN
Patent and Exclusivity Info for this product:	View

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Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

[1]

FDA Home[2]

Active Ingredient Search Results from "OB_Rx" table for query on "MIDODRINE HYDROCHLORIDE."

Appl No	TE Code[4]	RLD[5]	Active Ingredient	Dosage Form; Route	Strength	Proprietary Name	Applicant
A077746	AB	No	MIDODRINE HYDROCHLORIDE	TABLET; ORAL	10MG	MIDODRINE HYDROCHLORIDE	APOTEX INC
A077746	AB	No	MIDODRINE HYDROCHLORIDE	TABLET; ORAL	2.5MG	MIDODRINE HYDROCHLORIDE	APOTEX INC
A077746	AB	No	MIDODRINE HYDROCHLORIDE	TABLET; ORAL	5MG	MIDODRINE HYDROCHLORIDE	APOTEX INC
A076449	AB	No	MIDODRINE HYDROCHLORIDE	TABLET; ORAL	10MG	MIDODRINE HYDROCHLORIDE	IMPAX PHARMS
A076449	AB	No	MIDODRINE HYDROCHLORIDE	TABLET; ORAL	2.5MG	MIDODRINE HYDROCHLORIDE	IMPAX PHARMS
A076449	AB	No	MIDODRINE HYDROCHLORIDE	TABLET; ORAL	5MG	MIDODRINE HYDROCHLORIDE	IMPAX PHARMS
A076577	AB	No	MIDODRINE HYDROCHLORIDE	TABLET; ORAL	10MG	MIDODRINE HYDROCHLORIDE	MYLAN
A076577	AB	No	MIDODRINE HYDROCHLORIDE	TABLET; ORAL	2.5MG	MIDODRINE HYDROCHLORIDE	MYLAN
A076577	AB	No	MIDODRINE HYDROCHLORIDE	TABLET; ORAL	5MG	MIDODRINE HYDROCHLORIDE	MYLAN
A076514	AB	No	MIDODRINE HYDROCHLORIDE	TABLET; ORAL	10MG	MIDODRINE HYDROCHLORIDE	SANDOZ
A076514	AB	No	MIDODRINE HYDROCHLORIDE	TABLET; ORAL	2.5MG	MIDODRINE HYDROCHLORIDE	SANDOZ
A076514	AB	No	MIDODRINE HYDROCHLORIDE	TABLET; ORAL	5MG	MIDODRINE HYDROCHLORIDE	SANDOZ
A076725	AB	No	MIDODRINE HYDROCHLORIDE	TABLET; ORAL	10MG	ORVATEN	UPSHER SMITH
A076725	AB	No	MIDODRINE HYDROCHLORIDE	TABLET; ORAL	2.5MG	ORVATEN	UPSHER SMITH
A076725	AB	No	MIDODRINE HYDROCHLORIDE	TABLET; ORAL	5MG	ORVATEN	UPSHER SMITH

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4. http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm#Therapeutic Equivalence-Related Terms
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Search results from the "OB_Rx" table for query on "076514."

Active Ingredient:	MIDODRINE HYDROCHLORIDE
Dosage Form;Route:	TABLET; ORAL
Proprietary Name:	MIDODRINE HYDROCHLORIDE
Applicant:	SANDOZ
Strength:	2.5MG
Application Number:	A076514
Product Number:	001
Approval Date:	Sep 11, 2003
Reference Listed Drug	No
RX/OTC/DISCN:	RX
TE Code:	**AB**
Patent and Exclusivity Info for this product:	View

Active Ingredient:	MIDODRINE HYDROCHLORIDE
Dosage Form;Route:	TABLET; ORAL
Proprietary Name:	MIDODRINE HYDROCHLORIDE
Applicant:	SANDOZ
Strength:	5MG
Application Number:	A076514
Product Number:	002
Approval Date:	Sep 11, 2003
Reference Listed Drug	No
RX/OTC/DISCN:	RX
TE Code:	**AB**
Patent and Exclusivity Info for this product:	View

Active Ingredient:	MIDODRINE HYDROCHLORIDE
Dosage Form;Route:	TABLET; ORAL
Proprietary Name:	MIDODRINE HYDROCHLORIDE
Applicant:	SANDOZ
Strength:	10MG
Application Number:	A076514
Product Number:	003
Approval Date:	Jul 2, 2004
Reference Listed Drug	No
RX/OTC/DISCN:	RX
TE Code:	**AB**
Patent and Exclusivity Info for this product:	View

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Search results from the "OB_Rx" table for query on "076449."

Active Ingredient:	MIDODRINE HYDROCHLORIDE
Dosage Form;Route:	TABLET; ORAL
Proprietary Name:	MIDODRINE HYDROCHLORIDE
Applicant:	IMPAX PHARMS
Strength:	2.5MG
Application Number:	A076449
Product Number:	001
Approval Date:	May 27, 2004
Reference Listed Drug	No
RX/OTC/DISCN:	RX
TE Code:	**AB**
Patent and Exclusivity Info for this product:	View

Active Ingredient:	MIDODRINE HYDROCHLORIDE
Dosage Form;Route:	TABLET; ORAL
Proprietary Name:	MIDODRINE HYDROCHLORIDE
Applicant:	IMPAX PHARMS
Strength:	5MG
Application Number:	A076449
Product Number:	002
Approval Date:	May 27, 2004
Reference Listed Drug	No
RX/OTC/DISCN:	RX
TE Code:	**AB**
Patent and Exclusivity Info for this product:	View

Active Ingredient:	MIDODRINE HYDROCHLORIDE
Dosage Form;Route:	TABLET; ORAL
Proprietary Name:	MIDODRINE HYDROCHLORIDE
Applicant:	IMPAX PHARMS
Strength:	10MG
Application Number:	A076449
Product Number:	003
Approval Date:	Dec 16, 2005
Reference Listed Drug	No
RX/OTC/DISCN:	RX
TE Code:	**AB**
Patent and Exclusivity Info for this product:	View

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