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Home (index.cfm?resetfields=1) | Back to Search Results

Product Details for NDA 022063

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MYDAYIS (AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE)
3.125MG;3.125MG;3.125MG;3.125MG Marketing Status: Prescription

Active Ingredient: AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE
Proprietary Name: MYDAYIS

Dosage Form; Route of Administration: CAPSULE, EXTENDED RELEASE; ORAL
Strength: 3.125MG;3.125MG;3.125MG;3.125MG
Reference Listed Drug: Yes
Reference Standard: No
TE Code:
Application Number: N022063
Product Number: 001
Approval Date: Jun 20, 2017
Applicant Holder Full Name: SHIRE DEVELOPMENT LLC
Marketing Status: Prescription
Patent and Exclusivity Information (patent_info.cfm?Product_No=001&Appl_No=022063&Appl_type=N)

MYDAYIS (AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE)
6.25MG;6.25MG;6.25MG;6.25MG Marketing Status: Prescription

Active Ingredient: AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE
Proprietary Name: MYDAYIS
Dosage Form; Route of Administration: CAPSULE, EXTENDED RELEASE; ORAL
Strength: 6.25MG;6.25MG;6.25MG;6.25MG
Reference Listed Drug: Yes
Reference Standard: No
TE Code:
Application Number: N022063
Product Number: 002
Approval Date: Jun 20, 2017
Applicant Holder Full Name: SHIRE DEVELOPMENT LLC
Marketing Status: Prescription
Patent and Exclusivity Information (patent_info.cfm?Product_No=002&Appl_No=022063&Appl_type=N)

MYDAYIS (AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE

SULFATE)
9.375MG;9.375MG;9.375MG;9.375MG Marketing Status: Prescription

Active Ingredient: AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE
Proprietary Name: MYDAYIS
Dosage Form; Route of Administration: CAPSULE, EXTENDED RELEASE; ORAL
Strength: 9.375MG;9.375MG;9.375MG;9.375MG
Reference Listed Drug: Yes
Reference Standard: No
TE Code:
Application Number: N022063
Product Number: 003
Approval Date: Jun 20, 2017
Applicant Holder Full Name: SHIRE DEVELOPMENT LLC
Marketing Status: Prescription
Patent and Exclusivity Information (patent_info.cfm?Product_No=003&Appl_No=022063&Appl_type=N)

MYDAYIS (AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE)
12.5MG;12.5MG;12.5MG;12.5MG Marketing Status: Prescription

Active Ingredient: AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE
Proprietary Name: MYDAYIS
Dosage Form; Route of Administration: CAPSULE, EXTENDED RELEASE; ORAL
Strength: 12.5MG;12.5MG;12.5MG;12.5MG
Reference Listed Drug: Yes
Reference Standard: No
TE Code:
Application Number: N022063
Product Number: 004
Approval Date: Jun 20, 2017
Applicant Holder Full Name: SHIRE DEVELOPMENT LLC
Marketing Status: Prescription

Patent and Exclusivity Information (patent_info.cfm?Product_No=004&Appl_No=022063&Appl_type=N)

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Home (index.cfm?resetfields=1) | Back to Product Details

Additional Information about Patents

- Patent information is published on or after the submission date as defined in 21 CFR 314.53(d)(5).
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