



Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations


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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

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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

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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

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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


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