



# 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**

**(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**

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- 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.

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