Mydayis
(amphetamine mixed-salts)

NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Mydayis
- **Generic name:** Mixed salts of a single-entity amphetamine product
- **Pharmacological class:** CNS stimulant
- **Strength and Formulation:** 12.5mg, 25mg, 37.5mg, 50mg; extended-release caps
- **Manufacturer:** Shire
- **How supplied:** Caps—100
- **Legal Classification:** CII

MYDAYIS


ONCE-DAILY
NDC 54092-468-01
Mydayis™
(Mixed Salts of A Single-Entity Amphetamine Product)
Extended-Release Capsules
12.5 mg
100 Capsules
Do not substitute for Adderall XR.
Rx only
Shire
018576
LOT
EXP.
ONCE-DAILY
NDC 54092-471-01
Mydayis™
(Mixed Salts of A Single-Entity Amphetamine Product)
Extended-Release Capsules
25 mg
100 Capsules
Do not substitute for Adderall XR.
Rx only
Shire
018577
LOT
EXP.
ONCE-DAILY
NDC 54092-474-01
Mydayis™
(Mixed Salts of A Single-Entity Amphetamine Product)
Extended-Release Capsules
37.5 mg
100 Capsules
Do not substitute for Adderall XR.
Rx only
Shire
018578
LOT
EXP.
ONCE-DAILY
NDC 54092-477-01
Mydayis™
(Mixed Salts of A Single-Entity Amphetamine Product)
Extended-Release Capsules
50 mg
100 Capsules
Do not substitute for Adderall XR.
Rx only
Shire
018579
LOT
EXP.

Indications

- Attention deficit hyperactivity disorder (ADHD)

Limitations of Use

- Higher plasma exposure and rates of adverse reactions (eg, insomnia, decreased appetite) in patients ≤12yrs than ≥13yrs at the same dose

Dosage & Administration

- Swallow whole or may open and sprinkle contents onto applesauce, then consume immediately; do not chew beads
- Individualize
- Avoid late evening doses; give in the AM upon awakening

Dosage & Administration

- **13–17yrs:** initially 12.5mg once daily; may increase by 12.5mg at weekly intervals; max 25mg/day
- **18–55yrs:** initially 12.5mg or 25mg once daily; may increase by 12.5mg at weekly intervals; max 50mg/day
- **Do not substitute** for other amphetamine products on a mg-per-mg basis
- Switching from other amphetamine products: see full labeling

Dosage & Administration

- **Severe renal impairment:**
  - GFR 15–30mL/min/1.73m^2: initially 12.5mg daily; max 25mg/day or 12.5mg/day (for 13–17yrs) if tolerated
- **ESRD**
  - GFR <15mL/min/1.73m^2: not recommended

Considerations for Special Populations

- **Pregnancy:** Monitor for neonatal withdrawal symptoms
- **Nursing mothers:** Not recommended
- **Pediatric:** ≤12yrs: not established
- **Elderly:** No overall differences in safety or efficacy
- **Renal impairment:** See Dosage and Administration

Contraindications

- During or within 14 days of **MAOIs**

Warnings/Precautions

- Abuse potential (monitor)
- **Increased risk** of sudden death, stroke, and MI; assess for presence of cardiac disease before initiating
- **Avoid** in known structural cardiac abnormalities, cardiomyopathy, serious arrhythmias, coronary artery disease, and other cardiac problems

Warnings/Precautions

- Pre-existing psychotic disorder
- Bipolar disorder
- Screen for risk factors in developing manic episode prior to initiating
- Consider discontinuing if new psychotic/manic symptoms occur
- Seizure disorder; consider discontinue if occurs

Warnings/Precautions

- Monitor for serotonin syndrome; discontinue and treat if occurs
- Peripheral vasculopathy, including Raynaud's phenomenon; monitor for digital changes
- Monitor BP, HR, growth in children
- Reevaluate periodically
- Labor & delivery

Interactions

- **See Contraindications**
- Hypertensive crisis with MAOIs (eg, selegiline, isocarboxazid, phenelzine, tranylcypromine)

Interactions

- Increased risk of **serotonin syndrome** with serotonergic drugs (eg, SSRIs, SNRIs, TCAs, triptans, fentanyl, lithium, tramadol, tryptophan, buspirone, St. John’s wort), CYP2D6 inhibitors (eg, paroxetine, fluoxetine, quinidine, ritonavir); consider alternatives; if needed, initiate with lower doses and monitor

Interactions

- Potentiated by alkalinizers (eg, sodium bicarbonate, PPIs, acetazolamide, some thiazides); caution
- Antagonized by acidifiers (eg, guanethidine, reserpine, glutamic acid HCl, ascorbic acid, ammonium chloride, sodium acid phosphate, methenamine salts); increase dose

Interactions

- May potentiate TCAs, sympathomimetics (eg, desipramine, protriptyline); adjust dose or use alternatives
- Monitor effects when concomitant PPIs or cimetidine
- May interfere with urinary steroid levels

Adverse Reactions

- Insomnia
- Decreased appetite
- Decreased weight
- Irritability
- Nausea
- Also adults: dry mouth, increased heart rate, anxiety

Mechanism of Action

- Amphetamines are non-catecholamine sympathomimetic amines with CNS stimulant activity
- The exact mode of therapeutic action in ADHD is not known

Clinical Studies

- Mydayis was evaluated in 3 short-term trials in adults aged 18–55yrs **(Studies 1, 2, 3)** and in 2 short-term trials in pediatric patients aged 13–17yrs **(Studies 4, 5)**

Clinical Studies

- **Study 1** was a 4-week, randomized, double-blind, multicenter, placebo-controlled, forced-dose titration, safety and efficacy study (n=275)
- Adults were randomized to Mydayis 12.5mg/day (Group 1), Mydayis12.5mg titrated to 37.5mg/day (Group 2), or placebo (Group 3)

Clinical Studies

- The **primary efficacy endpoint** was the change from baseline of the adult ADHD-Rating Scale (RS) with prompts total score at Week 4
- Mydayis showed a statistically significant treatment effect vs. placebo on change of ADHD-RS total score from baseline at Visit 6 (Week 4) for both dose groups
  - Mean change: **-18.5** (Group 1) and **-23.8** (Group 2) vs. -10.4 (placebo)

Clinical Studies

- **Study 4** was a 4-week, randomized, double-blind, multi-center, placebo-controlled, dose-optimization, safety and efficacy study (n=157) in patients aged 13–17yrs
- Patients were randomized to Mydayis 12.5mg/day titrated to optimal dose (max 25mg) or placebo

Clinical Studies

- The **primary efficacy endpoint** was defined as the change from baseline of the ADHD-RS-IV Total Score at Week 4
- Mydayis showed a statistically significant treatment effect vs. placebo on the change of ADHD-RS-IV total scores from baseline at Visit 6 (Week 4)
  - Mean change: **-20.3** (Mydayis) vs. **-11.6** (placebo)

Clinical Studies

- Mydayis also showed statistically significantly greater improvement on the CGI-I score at Visit 6 (Week 4)

- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

http://www.empr.com/mydayis/drug/34726/