

# Quantity Limit

## Attention Deficit Hyperactivity Disorder (ADHD) Agents

### Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

#### Amphetamines

Brand Name	Generic Name	Dosage Form
Adzenys	amphetamine	all products
Dyanavel	amphetamine	all products
Evekeo	amphetamine	all products

#### Amphetamine-Dextroamphetamines

Brand Name	Generic Name	Dosage Form
Adderall	amphetamine-dextroamphetamine	all products
Mydayis	amphetamine-dextroamphetamine	all products

#### Dexmethylphenidates

Brand Name	Generic Name	Dosage Form
Azstarys	serdexmethylphenidate / dexmethylphenidate	all products

Brand Name	Generic Name	Dosage Form
Focalin	dexmethylphenidate	all products

## Dextroamphetamines

Brand Name	Generic Name	Dosage Form
Dexedrine	dextroamphetamine	all products
dextroamphetamine (all other brands)	dextroamphetamine	all products
ProCentra	dextroamphetamine	all products
Xelstrym	dextroamphetamine	all products
Zenzedi	dextroamphetamine	all products

## Lisdexamfetamines

Brand Name	Generic Name	Dosage Form
Arynta	lisdexamfetamine	all products
Vyvanse	lisdexamfetamine	all products

## Methamphetamines

Brand Name	Generic Name	Dosage Form
Desoxyn	methamphetamine	all products

## Methylphenidates

Brand Name	Generic Name	Dosage Form
Aptensio	methylphenidate	all products
Concerta	methylphenidate	all products
Cotempla	methylphenidate	all products
Daytrana	methylphenidate	all products
Jornay	methylphenidate	all products
Metadate	methylphenidate	all products
Methylin	methylphenidate	all products

Brand Name	Generic Name	Dosage Form
methylphenidate (all other brands)	methylphenidate	all products
QuilliChew	methylphenidate	all products
Quillivant	methylphenidate	all products
Relexxii	methylphenidate	all products
Ritalin	methylphenidate	all products

## Selective Norepinephrine Reuptake Inhibitors

Brand Name	Generic Name	Dosage Form
Qelbree	viloxazine	all products
Strattera	atomoxetine	all products

## Indications

### FDA-approved Indications

#### Adderall

Adderall is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) and Narcolepsy.

#### Adderall XR, Qelbree

These products are indicated for the treatment of attention deficit hyperactivity disorder (ADHD) in adults and pediatric patients 6 years and older.

#### Adzenys XR-ODT, Azstarys, Dyanavel XR, Jornay PM

These products are indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years and older.

#### Aptensio XR

Aptensio XR is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years and older.

#### Limitations of Use:

Pediatric patients younger than 6 years of age experienced higher plasma exposure than patients 6 years and older at the same dose and high rates of adverse reactions, most notably weight loss.

## Arynta, Vyvanse

These products are indicated for the treatment of:

- Attention Deficit Hyperactivity Disorder (ADHD) in adults and pediatric patients 6 years and older
- Moderate to severe binge-eating disorder (BED) in adults

### Limitations of Use:

- Pediatric patients with ADHD younger than 6 years of age experienced more long-term weight loss than patients 6 years and older.
- These products are not indicated or recommended for weight loss. Use of other sympathomimetic drugs for weight loss has been associated with serious cardiovascular adverse events. The safety and effectiveness of these products for the treatment of obesity have not been established.

## Concerta

Concerta is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in children 6 years of age and older, adolescents, and adults up to the age of 65.

## Cotempla XR-ODT, Daytrana, Evekeo ODT

These products are indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in pediatric patients 6 to 17 years of age.

## Desoxyn

Desoxyn is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in pediatric patients 6 years of age and older.

## Dexedrine Spansule

Dexedrine is indicated in:

- Narcolepsy
- Attention Deficit Disorder with Hyperactivity as an integral part of a total treatment program that typically includes other measures (psychological, educational, social) for patients (ages 6 years to 16 years) with this syndrome.

## Dextroamphetamine Sulfate Tablets, ProCentra, Zenzedi

Dextroamphetamine Sulfate is indicated for:

- Narcolepsy.
- Attention Deficit Disorder with Hyperactivity, as an integral part of a total treatment program which typically includes other remedial measures (psychological, educational, social) for a stabilizing effect in pediatric patients (ages 3 to 16 years) with a behavioral syndrome characterized by the following group of developmentally inappropriate symptoms: moderate to severe distractibility, short attention span, hyperactivity, emotional lability, and impulsivity.

## Evekeo

Evekeo (amphetamine sulfate tablets, USP) is indicated for:

- Narcolepsy
- Attention Deficit Disorder with Hyperactivity as an integral part of a total treatment program which typically includes other remedial measures (psychological, educational, social) for a stabilizing effect in children with behavioral syndrome characterized by the following group of developmentally inappropriate symptoms: moderate to severe distractibility, short attention span, hyperactivity, emotional lability, and impulsivity.
- Exogenous Obesity as a short term (a few weeks) adjunct in a regimen of weight reduction based on caloric restriction for patients refractory to alternative therapy, e.g., repeated diets, group programs, and other drugs. The limited usefulness of amphetamines should be weighed against possible risks inherent in use of the drug.

## Focalin, Focalin XR, QuilliChew ER, Quillivant XR

These products are indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

## Metadate CD

Metadate CD is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in pediatric patients 6 to 15 years of age.

## Methylin Oral Solution

Methylin is indicated for the treatment of:

- Attention Deficit Hyperactivity Disorder (ADHD) in adults and pediatric patients 6 years of age and older
- Narcolepsy

## Methylphenidate Chewable Tablets

### Attention Deficit Disorders

Methylphenidate hydrochloride chewable tablets are indicated as an integral part of a total treatment program which typically includes other remedial measures (psychological, educational, social) for a stabilizing effect in children with a behavioral syndrome characterized by the following group of developmentally inappropriate symptoms: moderate-to-severe distractibility, short attention span, hyperactivity, emotional lability, and impulsivity.

### Narcolepsy

## Methylphenidate Extended-Release, Ritalin

These products are indicated for the treatment of:

- Attention Deficit Hyperactivity Disorders (ADHD) in pediatric patients 6 years and older and adults
- Narcolepsy

## Methylphenidate LA, Ritalin LA

These products are indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD), in pediatric patients 6 to 12 years of age.

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## Methylphenidate Osmotic Extended-Release, Relexxii

These products are indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in adults (up to the age of 65 years) and pediatric patients 6 years of age and older.

## Mydayis

Mydayis is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 13 years and older.

### **Limitations of Use:**

Pediatric patients 12 years and younger experienced higher plasma exposure than patients 13 years and older at the same dose, and experienced higher rates of adverse reactions, mainly insomnia and decreased appetite.

## Strattera

Strattera is indicated for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD).

The efficacy of Strattera capsules was established in seven clinical trials in outpatients with ADHD; four 6 to 9-week trials in pediatric patients (ages 6 to 18), two 10-week trials in adults, and one maintenance trial in pediatrics (ages 6 to 15).

## Xelstrym

Xelstrym is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in adults and pediatric patients 6 years and older.

### **Limitations of Use:**

Pediatric patients younger than 6 years of age experienced more long-term weight loss than patients 6 years and older.

## Initial Limit Quantity

Limits do not accumulate together; patient is allowed the maximum limit for each drug and strength.

The duration of 21 days is used for a 28-day fill period and 63 days is used for an 84-day fill period to allow time for refill processing.

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

<b>Drug</b>	<b>Maximum Dose/24 hours (ADHD only)<sup>1-38</sup></b>	<b>1 Month Limit</b>	<b>3 Month Limit</b>
Adderall (amphetamine-dextroamphetamine) 5 mg, 7.5 mg, 10 mg, 12.5 mg	40 mg	90 tabs / 25 days	270 tabs / 75 days
Adderall (amphetamine-dextroamphetamine) 15 mg, 20 mg	40 mg	60 tabs / 25 days	180 tabs / 75 days
Adderall (amphetamine-dextroamphetamine) 30 mg	40 mg	30 tabs / 25 days	90 tabs / 75 days
Adderall XR (amphetamine-dextroamphetamine extended-release) 5 mg, 10 mg	30 mg	90 caps / 25 days	270 caps / 75 days
Adderall XR (amphetamine-dextroamphetamine extended-release) 15 mg, 20 mg, 25 mg, 30 mg	30 mg	30 caps / 25 days	90 caps / 75 days
Adzenys XR-ODT 3.1 mg, 6.3 mg, 9.4 mg	18.8 mg	60 tabs / 25 days	180 tabs / 75 days
Adzenys XR-ODT 12.5 mg, 15.7 mg, 18.8 mg	18.8 mg	30 tabs / 25 days	90 tabs / 75 days
Aptensio XR (methylphenidate extended-release) 10 mg, 15 mg, 20 mg, 30 mg	60 mg	60 caps / 25 days	180 caps / 75 days
Aptensio XR (methylphenidate extended-release) 40 mg, 50 mg, 60 mg	60 mg	30 caps / 25 days	90 caps / 75 days
Arynta oral solution 10 mg / mL	70 mg	200 mL / 21 days	600 mL / 63 days
Azstarys 26.1 mg / 5.2 mg, 39.2 mg / 7.8 mg, 52.3 mg / 10.4 mg	52.3 mg/10.4 mg	30 caps / 25 days	90 caps / 75 days
Concerta (methylphenidate osmotic extended-release) 18 mg, 27 mg, 36 mg	72 mg	60 tabs / 25 days	180 tabs / 75 days

<b>Drug</b>	<b>Maximum Dose/24 hours (ADHD only)<sup>1-38</sup></b>	<b>1 Month Limit</b>	<b>3 Month Limit</b>
Concerta (methylphenidate osmotic extended-release) 54 mg	72 mg	30 tabs / 25 days	90 tabs / 75 days
Cotempla XR-ODT 8.6 mg, 17.3 mg, 25.9 mg	51.8 mg	60 tabs / 25 days	180 tabs / 75 days
Daytrana (methylphenidate transdermal) Patch 10 mg, 15 mg, 20 mg, 30 mg	30 mg	30 patches / 25 days	90 patches / 75 days
Desoxyn (methamphetamine) 5 mg	25 mg	150 tabs / 25 days	450 tabs / 75 days
Dexedrine Spansule (dextroamphetamine sustained-release) 10 mg	40 mg	120 caps / 25 days	360 caps / 75 days
Dexedrine Spansule (dextroamphetamine sustained-release) 15 mg	40 mg	60 caps / 25 days	180 caps / 75 days
Dextroamphetamine extended-release 5 mg	40 mg	120 caps / 25 days	360 caps / 75 days
Dextroamphetamine 5 mg, 10 mg	40 mg	120 tabs / 25 days	360 tabs / 75 days
Dyanavel XR oral suspension 2.5 mg / mL	20 mg	240 mL / 25 days	720 mL / 75 days
Dyanavel XR tablets 5 mg, 10 mg	20 mg	60 tabs / 25 days	180 tabs / 75 days
Dyanavel XR tablets 15 mg, 20 mg	20 mg	30 tabs / 25 days	90 tabs / 75 days
Evekeo (amphetamine) 5 mg, 10 mg	40 mg	120 tabs / 25 days	360 tabs / 75 days
Evekeo ODT 5 mg, 10 mg	40 mg	120 tabs / 25 days	360 tabs / 75 days
Evekeo ODT 15 mg, 20 mg	40 mg	60 tabs / 25 days	180 tabs / 75 days
Focalin (dexmethylphenidate) 2.5 mg, 5 mg	20 mg	120 tabs / 25 days	360 tabs / 75 days
Focalin (dexmethylphenidate) 10 mg	20 mg	60 tabs / 25 days	180 tabs / 75 days



<b>Drug</b>	<b>Maximum Dose/24 hours (ADHD only)<sup>1-38</sup></b>	<b>1 Month Limit</b>	<b>3 Month Limit</b>
Focalin XR (dexamethylphenidate extended-release) 5 mg, 10 mg, 15 mg, 20 mg	40 mg	60 caps / 25 days	180 caps / 75 days
Focalin XR (dexamethylphenidate extended-release) 25 mg, 30 mg, 35 mg, 40 mg	40 mg	30 caps / 25 days	90 caps / 75 days
Jornay PM 20 mg, 40 mg	100 mg	60 caps / 25 days	180 caps / 75 days
Jornay PM 60 mg, 80 mg, 100 mg	100 mg	30 caps / 25 days	90 caps / 75 days
Metadate CD (methylphenidate extended-release [CD]) 10 mg, 20 mg, 30 mg	60 mg	60 caps / 25 days	180 caps / 75 days
Metadate CD (methylphenidate extended-release [CD]) 40 mg, 50 mg, 60 mg	60 mg	30 caps / 25 days	90 caps / 75 days
Methylin (methylphenidate) oral solution 5 mg / 5 mL	60 mg	1,800 mL / 25 days	5,400 mL / 75 days
Methylin (methylphenidate) oral solution 10 mg / 5 mL	60 mg	900 mL / 25 days	2,700 mL / 75 days
Methylphenidate chewable tablets 2.5 mg, 5 mg, 10 mg	60 mg	180 tabs / 25 days	540 tabs / 75 days
Methylphenidate extended-release 10 mg, 20 mg	60 mg	90 tabs / 25 days	270 tabs / 75 days
Methylphenidate extended-release (LA) 60 mg	60 mg	30 caps / 25 days	90 caps / 75 days
Methylphenidate Osmotic Extended-Release 45 mg, 63 mg, 72 mg	72 mg	30 tabs / 25 days	90 tabs / 75 days
Mydayis (amphetamine-dextroamphetamine extended-release) 12.5 mg, 25 mg	50 mg	60 caps / 25 days	180 caps / 75 days

<b>Drug</b>	<b>Maximum Dose/24 hours (ADHD only)<sup>1-38</sup></b>	<b>1 Month Limit</b>	<b>3 Month Limit</b>
Mydayis (amphetamine-dextroamphetamine extended-release) 37.5 mg, 50 mg	50 mg	30 caps / 25 days	90 caps / 75 days
ProCentra (dextroamphetamine) oral solution 5 mg / 5 mL	40 mg	1,200 mL / 25 days	3,600 mL / 75 days
Qelbree 100 mg, 150 mg, 200 mg	600 mg	90 caps / 25 days	270 caps / 75 days
QuilliChew ER 20 mg, 30 mg	60 mg	60 tabs / 25 day	180 tabs / 75 days
QuilliChew ER 40 mg	60 mg	30 tabs / 25 days	90 tabs / 75 days
Quillivant XR oral suspension 25 mg / 5 mL (5 mg / mL)	60 mg	360 mL / 25 days	1,080 mL / 75 days
Relexxii (methylphenidate osmotic extended-release) 18 mg, 27 mg, 36 mg	72 mg	60 tabs / 25 days	180 tabs / 75 days
Relexxii (methylphenidate osmotic extended-release) 54 mg	72 mg	30 tabs / 25 days	90 tabs / 75 days
Relexxii 45 mg, 63 mg, 72 mg	72 mg	30 tabs / 25 days	90 tabs / 75 days
Ritalin (methylphenidate) 5 mg, 10 mg	60 mg	180 tabs / 25 days	540 tabs / 75 days
Ritalin (methylphenidate) 20 mg	60 mg	90 tabs / 25 days	270 tabs / 75 days
Ritalin LA (methylphenidate extended-release (LA)) 10 mg, 20 mg, 30 mg	60 mg	60 caps / 25 days	180 caps / 75 days
Ritalin LA (methylphenidate extended-release (LA)) 40 mg	60 mg	30 caps / 25 days	90 caps / 75 days
Strattera (atomoxetine) 10 mg, 18 mg, 25 mg	100 mg	120 caps / 25 days	360 caps / 75 days
Strattera (atomoxetine) 40 mg	100 mg	60 caps / 25 days	180 caps / 75 days

<b>Drug</b>	<b>Maximum Dose/24 hours (ADHD only)<sup>1-38</sup></b>	<b>1 Month Limit</b>	<b>3 Month Limit</b>
Strattera (atomoxetine) 60 mg, 80 mg, 100 mg	100 mg	30 caps / 25 days	90 caps / 75 days
Vyvanse (lisdexamfetamine) 10 mg, 20 mg, 30 mg	70 mg	60 units / 25 days	180 units / 75 days
Vyvanse (lisdexamfetamine) 40 mg, 50 mg, 60 mg, 70 mg	70 mg	30 units / 25 days	90 units / 75 days
Xelstrym 4.5 mg, 9 mg, 13.5 mg, 18 mg	18 mg	30 transdermal systems / 25 days	90 transdermal systems / 75 days
Zenzedi (dextroamphetamine) 2.5 mg, 5 mg, 7.5 mg, 10 mg	40 mg	120 tabs / 25 days	360 tabs / 75 days
Zenzedi (dextroamphetamine) 15 mg, 20 mg	40 mg	60 tabs / 25 days	180 tabs / 75 days
Zenzedi (dextroamphetamine) 30 mg	40 mg	30 tabs / 25 days	90 tabs / 75 days

## References

1. Adderall [package insert]. Parsippany, NJ: Teva Pharmaceuticals; May 2024.
2. Adderall XR [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; October 2023.
3. Adzenys XR-ODT [package insert]. Grand Prairie, TX: Neos Therapeutics Brands, LLC; October 2023.
4. Aptensio XR [package insert]. Wilson, NC: Rhodes Pharmaceuticals; October 2023.
5. Arynta [package insert]. Woborn, MA: Azurity Pharmaceuticals, Inc.; June 2025.
6. Azstarys [package insert]. Boston, MA: Corium, LLC; October 2023.
7. Concerta [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; October 2023.
8. Cotempla XR-ODT [package insert]. Grand Prairie, TX: Neos Therapeutics Brands, LLC; June 2021.
9. Daytrana [package insert]. Miami, FL: Noven Therapeutics, LLC; April 2024.
10. Desoxyn [package insert]. Tampa, FL: Ajenat Pharmaceuticals, LLC.; September 2024.
11. Dexedrine Spansule [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; October 2023.
12. Dextroamphetamine sulfate [package insert]. Parsippany, NJ: Teva Pharmaceuticals; September 2023.
13. Dyanavel XR [package insert]. Monmouth Junction, NJ: Tris Pharma, Inc.; October 2023.
14. Evekeo [package insert]. Atlanta, GA: Arbor Pharmaceuticals, LLC; October 2023.
15. Evekeo ODT [package insert]. Atlanta, GA: Arbor Pharmaceuticals, LLC; October 2023.

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16. Focalin [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2023.
17. Focalin XR [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2023.
18. Jornay PM [package insert]. Morrisville, NC: Ironshore Pharmaceuticals Inc.; October 2023.
19. Metadate CD [package insert]. Denver, CO: Aytu BioPharma; October 2023.
20. Methylin Solution [package insert]. Florham Park, NJ: Shionogi Inc.; November 2023.
21. Methylphenidate Hydrochloride Chewable Tablets [package insert]. Lawrenceville, GA: XLCare Pharmaceuticals, Inc.; September 2023.
22. Methylphenidate Hydrochloride Extended Release Tablet [package insert]. Newtown, PA: KVK-Tech, Inc.; February 2024.
23. Methylphenidate Hydrochloride (LA) [package insert]. Raleigh, NC: Mayne Pharma; November 2022.
24. Methylphenidate Osmotic Extended Release [package insert]. Alpharetta, GA: Trigen Laboratories, LLC; October 2023.
25. Mydayis [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; October 2023.
26. ProCentra [package insert]. Newport, KY: Independence Pharmaceuticals, LLC; July 2023.
27. Qelbree [package insert]. Rockville, MD: Supernus Pharmaceuticals, Inc.; April 2022.
28. QuilliChew ER [package insert]. Monmouth Junction, NJ: NextWave Pharmaceuticals, Inc.; October 2023.
29. Quillivant XR [package insert]. Monmouth Junction, NJ: NextWave Pharmaceuticals, Inc.; October 2023.
30. Relexxii [package insert]. Alpharetta, GA: Vertical Pharmaceuticals, LLC; May 2024.
31. Ritalin [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2023.
32. Ritalin LA [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2023.
33. Strattera [package insert]. Indianapolis, IN: Lilly USA, LLC; January 2022.
34. Vyvanse [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; October 2023.
35. Xelstrym [package insert]. Miami, FL: Noven Pharmaceuticals, Inc.; October 2023.
36. Zenzedi [package insert]. Atlanta, GA: Arbor Pharmaceuticals, LLC; October 2023.
37. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed October 9, 2024.
38. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed October 9, 2024.
39. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 10/09/2024).