simtriyo®
centanafadine CIII
capsules 140 mg / 210 mg / 280 mg

ADHD symptoms have range. So does Simtriyo.

See inside for your guide to managing patient treatment



INDICATION and IMPORTANT SAFETY INFORMATION for SIMTRIYO® (centanafadine) CIII

INDICATION

Simtriyo is a norepinephrine-dopamine-serotonin reuptake inhibitor and central nervous system stimulant indicated for the treatment of ADHD in adults and pediatric patients 6 years of age and older weighing at least 20 kg.

Limitations of Use

The use of Simtriyo is not recommended in pediatric patients younger than 6 years of age, because this pediatric subpopulation had a higher incidence of weight loss than pediatric patients 6 years of age and older, or in pediatric patients weighing less than 20 kg, because of a lack of data for this subpopulation and the risk of weight loss.

WARNING: SUICIDAL IDEATION AND BEHAVIORS IN PEDIATRIC PATIENTS AGED 6 YEARS AND OLDER

Higher rates of suicidal ideation and behaviors occurred in Simtriyo-treated patients aged 6 to 12 years with attention-deficit/hyperactivity disorder (ADHD) than in placebo-treated patients. Closely monitor all pediatric patients for suicidal ideation and behaviors. Consider stopping Simtriyo in patients who experience emergent suicidal ideation and behavior.

WARNING: ABUSE, MISUSE, AND ADDICTION

Simtriyo has a potential for abuse and misuse. Abuse of central nervous system (CNS) stimulants, including Simtriyo, can lead to the development of a substance use disorder, including addiction. Misuse and abuse of CNS stimulants, including Simtriyo, can result in overdose and death. Before prescribing Simtriyo, assess each patient's risk for abuse, misuse, and addiction. Educate patients and their families about these risks, proper storage of Simtriyo, and proper disposal of any unused drug. Throughout treatment, reassess each patient's risk and frequently monitor for signs and symptoms of abuse, misuse, and addiction.

Please see additional Important Safety Information throughout and FULL PRESCRIBING INFORMATION, including BOXED WARNINGS.

ALL ABOUT SIMTRIYO

See what's possible with a novel approach to ADHD treatment

Simtriyo targets 3 neurotransmitters

As the first and only NDSRI (norepinephrine-dopamine-serotonin reuptake inhibitor) and CNS stimulant for the treatment of ADHD, Simtriyo is designed to address the needs of your patients.[1]

The mechanism of action of Simtriyo in the treatment of ADHD is unclear; however, its efficacy could be mediated through its activity as an NDSRI.[1]

Simtriyo was proven effective in reducing diagnostic symptoms

In clinical trials, Simtriyo was shown to improve the diagnostic symptoms of ADHD: inattention and hyperactivity/impulsivity.[1-4]

Additional endpoints studied effect of Simtriyo on associated features

A post hoc analysis studied the effect Simtriyo had on emotional dysregulation and executive dysfunction in adult patients. Key secondary and exploratory endpoints also studied executive dysfunction, learning problems, and other challenges in children and adolescents taking Simtriyo.[5-7]

Simtriyo has an established safety profile across clinical trials

In adult and pediatric clinical trials, Simtriyo showed low incidence of serious adverse events and low discontinuation rates.[1,2,4,5]

The most common adverse reactions (≥5% and greater than placebo) in the double-blind clinical trials were[1]:

- **Children aged 6 to 12 years:** rash,* decreased appetite
- **Adolescents aged 13 to 17 years:** decreased appetite, nausea, rash,* headache, abdominal pain
- **Adults:** headache, decreased appetite, insomnia, nausea, dry mouth, diarrhea

*Rash includes drug eruption, macular rash, maculopapular rash, morbilliform rash, papular rash, and other related terms.

IMPORTANT SAFETY INFORMATION (Cont'd)

Contraindications: Simtriyo is contraindicated in patients with a known hypersensitivity to centanafadine or any of the excipients of Simtriyo, taking or within 14 days of stopping a monoamine oxidase inhibitor, or with pheochromocytoma or a history of pheochromocytoma.

GET IN TOUCH

Explore educational resources to help your patients with ADHD get the care they need

Get resources to help you prescribe Simtriyo

We've provided a range of resources, including clinical data, safety and dosing information, and patient support materials.

Have questions? A Simtriyo representative can answer questions about prescribing and more.

Visit SimtriyoHCP.com for more information, including downloadable resources

IMPORTANT SAFETY INFORMATION (Cont'd)

Risks to Patients with Serious Cardiac Disease: Avoid use in patients with known structural cardiac abnormalities, cardiomyopathy, serious cardiac arrhythmia, coronary artery disease, or other serious cardiac disease.

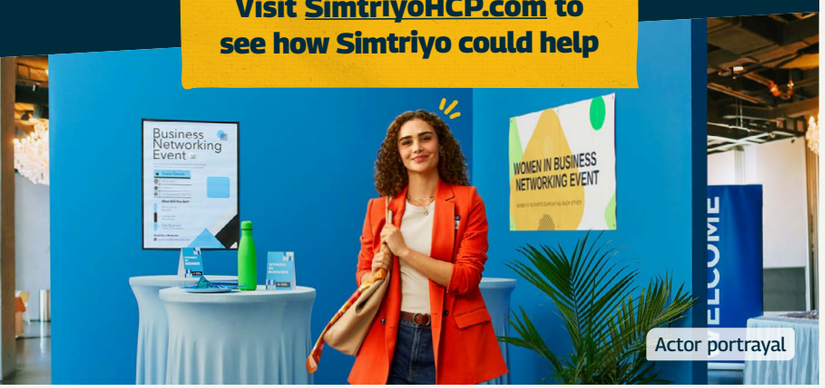
Increased Blood Pressure and Heart Rate: Assess heart rate and blood pressure following increases in dosage, and periodically while on therapy.

Psychiatric Adverse Reactions: If new psychotic or manic symptoms occur, consider discontinuing Simtriyo.

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Could Simtriyo be right for your patients with ADHD?

Visit SimtriyoHCP.com to see how Simtriyo could help



Actor portrayal

IMPORTANT SAFETY INFORMATION (Cont'd)

Hypersensitivity Reactions: Serious hypersensitivity, including anaphylaxis and angioedema, have been reported. If a clinically significant hypersensitivity reaction occurs, immediately discontinue Simtriyo and initiate appropriate therapy.

Long-Term Suppression of Growth in Pediatric Patients: Closely monitor height, body mass index and linear growth in pediatric patients. Consider treatment interruption in patients not growing or gaining height or weight as expected.

Peripheral Vasculopathy Including Raynaud's Phenomenon: Carefully assess for digital changes during Simtriyo treatment. Further clinical evaluation (e.g., rheumatology referral) may be appropriate for patients who develop signs or symptoms of peripheral vasculopathy.

Serotonin Syndrome: Use of Simtriyo with other serotonergic drugs may cause serotonin syndrome. If occurs, discontinue Simtriyo and/or concomitant serotonergic drug.

Motor and Verbal Tics and Worsening of Tourette's Syndrome: Regularly monitor patients for the emergence or worsening of tics or Tourette's syndrome. Discontinue Simtriyo if clinically appropriate.

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SIMTRIYO DOSING

With Simtriyo, there's no titration required. For most patients, the starting dose is the therapeutic dose[1]

Simtriyo once-daily dosing at a glance[1]

Adults*
18 and up

Recommended	Dose (mg)
Starting	210
Maximum	280

*In adults, the recommended dosage of Simtriyo is 210 mg orally once daily. The dosage may be increased to the maximum recommended dosage of 280 mg once daily based on clinical response and tolerability.

Adolescents†

Years of age	Dose (mg)
13-17	280

†In patients aged 13 to 17 years, the effectiveness of Simtriyo 140 mg once daily was not established, and Simtriyo 210 mg once daily has not been studied and is not recommended.

Children
6-12 years of age (based on weight)

Weight (kg)	Dose (mg)
20-<35	140
35-50	210
>50	280

IMPORTANT SAFETY INFORMATION (Cont'd)

Most commonly observed adverse reactions (≥5% and greater than placebo): The most common adverse reactions in pediatric patients (aged 6 to 12 years) were rash and decreased appetite, and (aged 13 to 17 years) decreased appetite, nausea, rash, headache, and abdominal pain. The most common adverse reactions in adults were headache, decreased appetite, insomnia, nausea, dry mouth, and diarrhea.

Pregnant women exposed to Simtriyo and healthcare providers are encouraged to contact the National Pregnancy Registry for ADHD Medications at 1-866-961-2388 or visiting https://womensmentalhealth.org/research/pregnancyregistry/adhd-medications/

SUPPORT & SAVINGS

Help patients access Simtriyo for their ADHD

Request Simtriyo samples for your practice

Once you identify appropriate patients for Simtriyo, you can request samples from Otsuka to help get your patients started on treatment. Samples are available in doses of 140 mg, 210 mg, and 280 mg.

Authorization support

CoverMyMeds® (a third-party service contracted by Otsuka) helps your eligible* patients with coverage support.
For more information, visit CoverMyMeds.com

*Further conditions apply.

simtriyo GO

Copay savings card

Eligible† commercially insured patients **may pay as little as $20** per prescription through the Simtriyo GO Savings Program.

Fulfillment support

Otsuka is committed to providing information and support to help patients stay on track with treatment. Patients may receive calls or texts with updates on prescription status and insurance approval.

†Additional Terms and Conditions apply. Please see the full Terms and Conditions at SimtriyoHCP.com/savings-support.

IMPORTANT SAFETY INFORMATION (Cont'd)

To report SUSPECTED ADVERSE REACTIONS, contact Otsuka America Pharmaceutical, Inc. at 1-800-438-9927 or FDA at 1-800-FDA-1088 (www.fda.gov/medwatch).

References: 1. Simtriyo Prescribing Information. Otsuka America Pharmaceutical Inc. 2026. **2.** Adler LA, et al. Efficacy, safety, and tolerability of centanafadine sustained-release tablets in adults with attention-deficit/hyperactivity disorder. *J Clin Psychopharmacol.* 2022;42(5):429-439. **3.** Ward CL, et al. Centanafadine for attention-deficit/hyperactivity disorder in adolescents: a randomized clinical trial. *J Am Acad Child Adolesc Psychiatry.* Published online July 4, 2025. doi:10.1016/j.jaac.2025.06.023. **4.** Ward CL, et al. Efficacy and safety of centanafadine for ADHD treatment in children: a randomized clinical trial. *Pediatr Open Sci.* 2025;1(3):1-11. **5.** Newcorn JH, et al. Emotional dysregulation symptom outcomes in adults with ADHD treated with centanafadine: a pooled post hoc analysis of two phase 3 trials. Poster presented at: 2026 American Society of Clinical Psychopharmacology (ASCP) Annual Meeting; May 26-29, 2026; Miami Beach, FL. **6.** Newcorn JH, et al. Executive function symptom outcomes in adults with ADHD treated with centanafadine: a pooled post hoc analysis of two phase 3 trials. Poster presented at: 2026 American Society of Clinical Psychopharmacology (ASCP) Annual Meeting; May 26-29, 2026; Miami Beach, FL. **7.** Oberdhan D, et al. Efficacy of centanafadine on the Conners 3-Learning Problems Content Scale in pediatric patients with attention-deficit/hyperactivity disorder. Poster presented at: Psych Congress 2024; October 29-November 2, 2024; Boston, MA.