What you need to know about getting started on Simtriyo

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

Simtriyo is the first-and-only FDA-approved ADHD treatment designed to target 3 neurotransmitters—norepinephrine, dopamine, and serotonin—which may play a role in attention, behavior, and mood.

For even more information, visit Simtriyo.com.



Simtriyo is a stimulant that's approved for adults, teens, and kids aged 6 and older weighing at least 44 lbs (20 kg). Simtriyo is not recommended in patients younger than 6 or weighing less than 20 kg due to risk of weight loss.

Welcome to a different kind of ADHD treatment.



Here's some key information about taking Simtriyo:

- It's important to take Simtriyo as prescribed and ask your doctor any questions you have along the way.
- Because everyone's experience with ADHD is different, talk to your doctor about setting goals for you or your child's treatment.
- Simtriyo releases medication in the body gradually throughout the day.
- It's designed to work differently for a wide range of symptoms. Talk to your doctor if you have any questions, including when you may start to feel a difference in symptoms.
- Keep track of the effect Simtriyo is having on your ADHD symptoms, so you can discuss these differences with your doctor at follow-up appointments.

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

WARNING: SUICIDAL THOUGHTS AND ACTIONS IN CHILDREN 6 YEARS OF AGE AND OLDER.
Suicidal thoughts and actions can happen in children 6 years of age and older with attention deficit hyperactivity disorder (ADHD), especially within the first few months of treatment. Tell your healthcare provider right away about any changes, especially sudden changes in mood, behavior, thoughts or feelings, or suicidal thoughts or actions.

WARNING: ABUSE, MISUSE, AND ADDICTION
Simtriyo has a chance for abuse and misuse and may lead to substance use problems, including addiction. Misuse and abuse of Simtriyo can lead to overdose and death. This risk is increased with higher doses of Simtriyo or when it is used in ways that are not approved, such as snorting or injection. Your healthcare provider will check you or your child's risk for abuse, misuse, and addiction before starting treatment with Simtriyo and will frequently monitor you or your child throughout treatment. Keep Simtriyo in a safe place and properly dispose of any unused medicine.

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

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How should I take Simtriyo?

Simtriyo is designed to fit into your daily life, not complicate it.



Once daily in the morning—with or without food.



Do not drink alcohol at the same time or within 2 hours of taking Simtriyo.



Don't cut, crush, or chew the capsule.



If swallowing is tough, open and mix into applesauce, yogurt, or juice—and drink water right after.



Missed a dose?

Take it as soon as you remember, but no later than 4 hours after the normal time. Don't take more than 1 dose in the same day. You can always contact your doctor with questions.

As you begin treatment, talk with your doctor about any questions or concerns you may have, including side effects or how you are feeling.

IMPORTANT SAFETY INFORMATION (Cont'd)

Do not take Simtriyo if you or your child:

- are allergic to centanafadine or any of the ingredients in Simtriyo. See the end of this Medication Guide for a complete list of ingredients in Simtriyo.
- are taking, or have stopped taking within the past 14 days, a medicine called a monoamine oxidase inhibitor (MAOI).
- have a condition called pheochromocytoma (a rare tumor that usually grows in the adrenal glands which are above your kidneys).

Simtriyo may cause serious side effects, including:

- **Risks in people with serious heart disease.** Sudden death has happened in people who have heart defects or other serious heart disease. Your healthcare provider should check you or your child carefully for heart problems before starting treatment with Simtriyo. Tell your healthcare provider or go to the nearest emergency room right away if any signs of heart problems develop such as chest pain, shortness of breath, or fainting.
- **Increased blood pressure and heart rate.** Your healthcare provider should check you or your child's blood pressure and heart rate before starting treatment, if the dose is increased, and as needed during treatment with Simtriyo.

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Your guide to savings with Simtriyo GO



simtriyo Go

1. Your prescription is sent to your pharmacy

- Your pharmacy may contact you to confirm your insurance. Be sure to answer these calls or texts to avoid delays.

2. Enroll in the Simtriyo GO Savings Program*

- Eligible commercially insured patients can get started on treatment and stay on treatment for **as little as $20 for a 30-day supply.**
- Savings can be applied while waiting for insurance decision.
- Simtriyo GO Savings Card works for both new prescriptions and refills.

Enroll in the Simtriyo GO Savings Program at **Simtriyo.com/save**

3. Pick up your medication

- Your pharmacy will let you know when your medication is ready.
- Make sure you have your Simtriyo GO Savings Card and bring it to the pharmacy.

Your healthcare provider and pharmacy will work together to support your access to treatment if insurance approval is required.

Experiencing delays?

Contact your healthcare provider's office or your pharmacy.

We're here to help

Additional questions? Call Simtriyo GO at **844-3Simtri (844-374-6874)**.

*Restrictions apply. Eligible patients may pay as little as $20 for a 30-day supply of Simtriyo® with a maximum savings of wholesale acquisition cost plus usual and customary pharmacy charges and an annual maximum of 13 uses per calendar year. Benefit cap applies regardless of copay amount.

Eligible patients with commercial insurance that do not have coverage for Simtriyo may pay as little as $20 for up to four (4) 30-day supplies per lifetime. See full Terms and Conditions for more information at Simtriyo.com/savings-support.

IMPORTANT SAFETY INFORMATION (Cont'd)

- **Mental problems (psychiatric reactions), including:**
  - worsening behavior or thought problems in people with thought or psychotic disorders
  - manic episodes in people with bipolar disorder
  - new psychotic or manic symptoms in people without bipolar or psychotic disorders

Tell your healthcare provider right away if any mental symptoms or problems develop or worsen during treatment with Simtriyo, including:

- greatly increased energy
- racing thoughts
- unusually grand ideas
- talking more or faster than usual
- severe trouble sleeping
- reckless behavior
- excessive happiness or irritability
- seeing or hearing things that are not real (hallucinations).

- **Allergic reactions, including serious allergic reactions (anaphylaxis).** Serious allergic reactions can happen during treatment with Simtriyo and can lead to hospitalization. Your healthcare provider may stop treatment with Simtriyo if you develop allergic reactions. Tell your healthcare provider right away if you get any signs or symptoms including:
  - raised, red areas on your skin (hives)
  - skin redness or rash, itching, flaking, or peeling
  - dizziness or fainting
  - swelling of face, eyes, lips, throat, or other areas
  - difficulty in breathing or swallowing

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IMPORTANT SAFETY INFORMATION (Cont'd)

- **Slowing of growth (height and weight) in children.** Children should have their height and weight checked often during treatment with Simtriyo. Simtriyo treatment may be stopped if your child is not growing or gaining weight as expected.
- **Circulation problems in fingers and toes (peripheral vasculopathy, including Raynaud's phenomenon).** Tell your healthcare provider if any of the following signs and symptoms of circulation problems develop during treatment:
  - fingers or toes feel numb, cool, painful
  - fingers or toes change color from pale, to blue, to red
  - sensitivity to temperature in fingers or toes

  Call your healthcare provider right away if any unexplained wounds appear on the fingers or toes during treatment with Simtriyo.
- **Serotonin Syndrome.** A potentially life-threatening problem called serotonin syndrome can happen when you take Simtriyo with certain other medicines. Stop taking Simtriyo and tell your healthcare provider or go to the nearest hospital emergency room right away if any of the following signs and symptoms develop during treatment:
  - agitation
  - confusion
  - fast heartbeat
  - dizziness
  - flushing
  - tremors, stiff muscles, or muscle twitching
  - seizures
  - coma
  - changes in blood pressure
  - sweating
  - high body temperature (hyperthermia)
  - loss of coordination
  - nausea, vomiting, diarrhea
  - seeing or hearing things that are not real (hallucinations)
- **New or worsening tics or worsening Tourette's syndrome.** Tell your healthcare provider if any new or worsening tics or worsening Tourette's syndrome symptoms develop during treatment with Simtriyo.
- **Allergic reactions to FD&C Yellow No. 5.** Simtriyo 210 mg capsules contain a yellow food dye called tartrazine (FD&C No. 5) which may cause allergic-type reactions (including bronchial asthma) in certain people. If you are allergic to aspirin, you may be more likely to react to tartrazine. Tell your healthcare provider if any symptoms of allergic reactions develop during treatment, including hives, rash, swelling, or trouble breathing.

Before taking Simtriyo, tell your healthcare provider about all of your medical conditions, including if you or your child:

- have heart problems, heart disease, heart defects, or have a family history of sudden death, or high blood pressure
- have mental problems including psychosis, mania, bipolar illness, or depression, or have a family history of suicide, bipolar illness, or depression
- have circulation problems in fingers and toes
- have or had uncontrolled movements or sounds (tics) or Tourette's syndrome, or have a family history of tics or Tourette's syndrome
- have an allergy or sensitivity to FD&C Yellow No. 5 (tartrazine)
- have liver problems
- are pregnant or plan to become pregnant. It is not known if Simtriyo will harm the unborn baby. Talk to your healthcare provider about the risk to the unborn baby if you or your child take Simtriyo during pregnancy.
  - If you or your child become pregnant during treatment with Simtriyo, talk to your healthcare provider about registering with the National Pregnancy Registry for ADHD Medications at 1-866-961-2388 or visiting online at https://womensmentalhealth.org/research/pregnancyregistry/adhd-medications/.
- are breastfeeding or plan to breastfeed. It is not known if Simtriyo passes into the breast milk. Talk to your healthcare provider about the best way to feed the baby during treatment with Simtriyo.

Tell your healthcare provider about all the medicines that you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Simtriyo and certain other medicines may affect each other causing possible serious side effects.

Especially tell your healthcare provider if you or your child take:

- a MAOI, including linezolid or intravenous methylene blue
- medicines used to treat mood, anxiety, psychotic or thought disorders, including selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), and tricyclic antidepressants
- medicines used to treat migraine headaches called triptans
- tramadol, fentanyl, meperidine, methadone, or other opioids
- tryptophan
- St. John's Wort
- other central nervous system (CNS) stimulants including other ADHD medicines

The most common side effects of Simtriyo include:

- **Children Aged:**
  - **6 to 12 Years:** rash, decreased appetite
  - **13 to 17 Years:** decreased appetite, nausea, rash, headache, stomach area (abdominal) pain
- **Adults:** headache, decreased appetite, trouble sleeping (insomnia), nausea, dry mouth, diarrhea

These are not all the possible side effects of Simtriyo. For more information, ask your healthcare provider or pharmacist.

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).

INDICATION

Simtriyo is a prescription medicine used to treat attention deficit hyperactivity disorder (ADHD) in adults and children 6 years of age and older weighing at least 44 pounds (20 kg).

Simtriyo is not recommended for use in children under 6 years of age or weighing less than 44 pounds (20 kg).

Simtriyo is a federally controlled substance (CIII) because it contains centanafadine, which can be a target for people who abuse prescription medicines or street drugs.

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

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