



Starting OGSIVEO

Important Patient Information¹

If you are considering or starting treatment with OGSIVEO, it's important to understand what to expect with your medicine.

What is OGSIVEO?

OGSIVEO is a prescription medication used to treat adults with progressing desmoid tumors who require a medicine by mouth or injection (systemic therapy). It is not known if OGSIVEO is safe and effective in children.

Important Safety Information

OGSIVEO can cause serious side effects, including diarrhea, ovarian problems, liver problems, new non-melanoma skin cancers, and electrolyte (salt) problems.

Please see full Prescribing Information and Patient Information for OGSIVEO.

Learn the meaning of *progressing* and *systemic therapy* in the Glossary on [page 13](#).

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Before taking OGSIVEO

Tell your healthcare provider about all of your medical conditions, including if you:

- Have liver problems
- Are pregnant or plan to become pregnant. OGSIVEO can harm your unborn baby. Tell your healthcare provider if you become pregnant or think you may be pregnant during treatment with OGSIVEO



Females who are able to become pregnant:

- Your healthcare provider will give you a pregnancy test before you start treatment with OGSIVEO
- You should use effective birth control (contraception) during treatment with OGSIVEO and for 1 week after the last dose. Talk to your healthcare provider about birth control methods that may be right for you
- Stop taking OGSIVEO and tell your healthcare provider right away if you become pregnant



Males with female partners who are able to become pregnant should use effective birth control (contraception) during treatment with OGSIVEO and for 1 week after the last dose.

- Are breastfeeding or plan to breastfeed. It is not known if OGSIVEO passes into your breast milk. Do not breastfeed during treatment with OGSIVEO and for 1 week after the last dose

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

You should avoid taking proton pump inhibitors (PPIs) and H2 blockers during treatment with OGSIVEO. Ask your healthcare provider if you are not sure if you take one of these medicines.

See [page 10](#) for important questions to ask your doctor.

Please see [full Prescribing Information](#) and [Patient Information](#) for OGSIVEO.

Learn the meanings of relevant medical words and phrases in the Glossary on [page 13](#).

Ogsiveo[™]
(nirogacestat)
50 mg tablets

What are desmoid tumors?

Desmoid tumors are dense, soft-tissue tumors. They can grow aggressively and affect nearby tissues and organs. They can often return, even after surgery or other treatments. A desmoid tumor is also called *aggressive fibromatosis*. Only 3% of soft-tissue tumors are desmoid tumors. It is a rare tumor type.²⁻⁵



In the US, **up to 1650 people** are diagnosed with desmoid tumors **every year.**⁶⁻⁸



Women are more likely to be diagnosed with desmoid tumors, but men are at risk as well.^{7,9,10}



The majority of people with desmoid tumors are diagnosed in **young adulthood.**⁷



After surgery, desmoid tumors **may come back**—based on the tumor location and other factors.^{10,11}

Desmoid tumors can affect each person differently depending on where the tumor is in the body, how fast it grows, and other factors.

Learn the meanings of relevant medical words and phrases in the Glossary on [page 13](#).

What are desmoid tumors? (continued)



The risk of desmoid tumors rises for people with a family history of *familial adenomatous polyposis (FAP)*.¹² If a person has FAP, doctors may recommend a *colectomy* to help prevent colon cancer. However, for some, this surgery can increase the risk of developing desmoid tumors.⁵



Desmoid tumors can develop anywhere in the body where there is soft, connective tissue.³ For example: Tumors may form in tissues within the *abdominal area*, the chest, legs and feet, arms and hands, or the head and neck.⁵



Desmoid tumors do not spread to other parts of the body (*metastasize*). However, even though they are not *malignant*, they can cause serious health problems as they grow. They can affect and damage surrounding organs, muscles, blood vessels, and nerves.^{2,3}



Desmoid tumor symptoms can vary based on where the tumor is located. For example: A tumor within the abdominal area may cause digestive system blockages, pain, malaise, abdominal swelling, weight loss, or muscle wasting.^{5,13,14} Tumors in the arms or legs may cause limited movement, deformity, pain, or muscle problems.^{5,15,16}

Monitor your symptoms

Monitor your symptoms regularly and report them to your healthcare provider. This may help them track your progress and manage your care plan. Various health apps may be available to track your symptoms on your smart phone.

Learn the meanings of relevant medical words and phrases in the Glossary on [page 13](#).

About OGSIVEO

OGSIVEO is the
first&only
... treatment ...

FDA-approved for adults with progressing desmoid tumors who require a medicine by mouth or injection (systemic therapy).

OGSIVEO is an oral medication that you can take at home.



Tablets shown are not actual size.



Take OGSIVEO exactly as your healthcare provider tells you to take it

Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with OGSIVEO if you develop side effects.

- OGSIVEO comes in 50 mg tablets
- The recommended dosage of OGSIVEO is three 50 mg tablets, 2 times a day—a **total of 6 tablets**
- OGSIVEO can be taken **with or without food**
- Swallow OGSIVEO tablets whole. Do not break, crush, or chew tablets
- If you take an antacid medicine, take OGSIVEO 2 hours before or 2 hours after taking the antacid
- If you vomit after taking a dose or miss a dose of OGSIVEO, take your next dose at your regular time. Do not take 2 doses of OGSIVEO to make up the dose
- **Tell your doctor about all the medicines you take**—including prescription and over-the-counter medicines, vitamins, and herbal supplements



What should I avoid while taking OGSIVEO?

- Avoid eating or drinking grapefruit products, Seville oranges, and starfruit during treatment with OGSIVEO
- You should avoid taking proton pump inhibitors (PPIs) and H2 blockers during treatment with OGSIVEO. Ask your healthcare provider if you are not sure if you take one of these medicines



Storing OGSIVEO

- Store OGSIVEO tablets at room temperature between 68°F to 77°F (20°C to 25°C)
- **Keep OGSIVEO and all medicines out of reach of children**

Please see **full Prescribing Information and Patient Information for OGSIVEO.**

Learn the meanings of relevant medical words and phrases in the Glossary on [page 13](#).

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(nirogacestat)
50 mg tablets

What are the possible side effects of OGSIVEO?

OGSIVEO can cause serious side effects, including:



Diarrhea. Diarrhea is common during treatment with OGSIVEO and may sometimes be severe. Your healthcare provider may tell you to drink more fluids, or may tell you to take antidiarrheal medicines. Tell your healthcare provider right away if you have diarrhea that lasts longer than a few days and does not get better after taking antidiarrheal medicines.



Ovarian problems. Females who are able to become pregnant may have ovarian problems and changes in their menstrual cycle during treatment with OGSIVEO. OGSIVEO may affect fertility which may affect your ability to have a child. Tell your healthcare provider if you have any changes in your menstrual cycle or any hot flashes, night sweats, or vaginal dryness during treatment with OGSIVEO.



Liver problems. OGSIVEO can cause an increase in liver enzymes. Your healthcare provider will do blood tests to check your liver function before you start and during your treatment with OGSIVEO.



New non-melanoma skin cancers. Your healthcare provider will do skin exams before and during treatment with OGSIVEO if you are at risk for skin cancer. Tell your healthcare provider if you have any new or changing skin lesions.

Continued on next page

Please see full Prescribing Information and Patient Information for OGSIVEO.

Learn the meanings of relevant medical words and phrases in the Glossary on [page 13](#).

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What are the possible side effects of OGSIVEO? (continued)



Electrolyte (salt) problems. Your healthcare provider will do blood tests to check your phosphate and potassium levels during treatment with OGSIVEO and may give you medicines to treat low phosphate or low potassium if needed. Tell your healthcare provider if you develop any muscle pain or weakness.

Tell your healthcare provider right away if you have any side effect that bothers you or that does not go away. Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with OGSIVEO.

The most common side effects of OGSIVEO are:

- Rash
- Nausea
- Tiredness
- Mouth sores
- Headache
- Stomach (abdominal) pain
- Cough
- Hair loss
- Upper respiratory infection
- Shortness of breath

OGSIVEO can affect fertility in females and males, which may affect your ability to have a child. Talk to your healthcare provider if this is a concern for you.

These are not all of the possible side effects of OGSIVEO. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Please see [full Prescribing Information](#) and [Patient Information](#) for OGSIVEO.

Learn the meanings of relevant medical words and phrases in the Glossary on [page 13](#).



General information about safe and effective use of OGSIVEO

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use OGSIVEO for a condition for which it is not prescribed. Do not give OGSIVEO to other people even if they have the same symptoms you have. It may harm them. You can ask your healthcare provider or pharmacist for information about OGSIVEO that is written for health professionals.

What are the ingredients in OGSIVEO?

Active Ingredient:

nirogacestat

Inactive Ingredients:

lactose monohydrate, magnesium stearate, microcrystalline cellulose, and sodium starch glycolate type A.

Film Coat Ingredients:

FD&C yellow #6/sunset yellow FCF aluminum lake, glycerol monocaprylocaprate type 1/mono/diglycerides, iron oxide yellow, macrogol (PEG) polyvinyl alcohol graft copolymer, polyvinyl alcohol - partially hydrolyzed, talc, and titanium dioxide.

Please see full Prescribing Information and Patient Information for OGSIVEO.

Learn the meanings of relevant medical words and phrases in the Glossary on [page 13](#).



Start the conversation with your healthcare provider

Understanding what to expect on OGSIVEO

Ask your healthcare provider any questions you may have about taking OGSIVEO. You may want to start with these:



1

How could starting OGSIVEO affect my daily life?

2

How would you and the care team monitor my treatment with OGSIVEO?

3

What should I do if I experience side effects?

Tips for taking medication:

- Add taking your medication to your daily routine, like before or after brushing your teeth¹⁷
- Use a pill container to help keep track of when to take your medication¹⁷
- When traveling, bring enough of your medication plus a few days' extra just in case¹⁷

Sign up for resources and support at
[OGSIVEO.com](https://www.ogsiveo.com)

Please see [full Prescribing Information](#) and [Patient Information](#) for OGSIVEO.

Learn the meanings of relevant medical words and phrases in the Glossary on [page 13](#).

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Connecting you to support on your treatment journey with OGSIVEO

Need assistance getting started on or staying on track with OGSIVEO?

SpringWorks CareConnections™ is a free, personalized patient support program to help you navigate your insurance coverage and answer questions about your treatment.



Insurance Navigation and Financial Help

- The SpringWorks CareConnections Nurse Advocates can offer information about financial assistance options, as well as information that explains your insurance coverage
- Commercially insured patients may **pay as little as a \$0 copay** through the Commercial Copay Program, for each OGSIVEO prescription*



Personalized Educational and Emotional Support for Patients Starting OGSIVEO

- The SpringWorks CareConnections team of dedicated Nurse Advocates can provide you with ongoing, personalized support no matter where you are in your treatment journey with OGSIVEO
- If you have started taking OGSIVEO, you can count on support from your Nurse Advocate to help keep you on track with your treatment

For questions and further information on the support available through SpringWorks CareConnections, please call 844-CARES-55 (844-227-3755), Monday – Friday 8 AM – 10 PM ET or visit www.springworkstxcare.com

*Terms and conditions apply. Copay program is subject to an annual benefit maximum. Full terms and conditions provided during enrollment process and are available upon request by contacting SpringWorks CareConnections at 844-CARES-55 (844-227-3755).

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Advocacy groups for additional desmoid tumor resources*

You may find it helpful to reach out to the organizations listed below for information, support, or to connect with others who are living with desmoid tumors.



The Desmoid Tumor Research Foundation (DTRF)

www.dtrf.org



Global Genes

www.globalgenes.org



National Organization for Rare Disorders (NORD)

www.rarediseases.org



Northwest Sarcoma Foundation

www.nwsarcoma.org



Rein in Sarcoma

www.reininsarcoma.org



Sarcoma Alliance for Research through Collaboration (SARC)

www.sarc trials.org



Sarcoma Foundation of America (SFA)

www.curesarcoma.org

*SpringWorks Therapeutics, Inc. is providing these links to help patients find more information about desmoid tumors, but inclusion on this list does not represent an endorsement or a recommendation from SpringWorks for any group or organization. These organizations are independent of SpringWorks Therapeutics, Inc.

Learn the meanings of relevant medical words and phrases in the Glossary on [page 13](#).

Glossary*

Abdominal area: The area inside the body that includes the stomach, the small and large intestines, liver, spleen, gallbladder, and pancreas, the uterus, fallopian tubes, and ovaries, the kidneys, ureters, bladder, and blood vessels.¹⁸

Colectomy: Surgery to remove all or part of the colon.

Connective tissue: Tissue that supports, protects, and gives structure to other tissues and organs in the body. Bone, cartilage, fat, blood, and lymphatic tissue are all types of connective tissue.

Desmoid tumors: Soft-tissue tumors that form in the connective tissues. (The tissues that connect, support, and protect other tissues and organs in the body.) For example, in the arms, legs, abdomen, head, or neck. Desmoid tumors do not metastasize, but are locally aggressive—which means they can affect nearby tissues and organs as they grow. They often come back even after treatment. A desmoid tumor is also called *aggressive fibromatosis* and *desmoid-type fibromatosis*.^{2,3}

Electrolytes: Minerals with an electrical charge (also known as ions) like sodium, potassium, and phosphate. The body needs electrolytes to help keep the muscles, nerves, heart, and brain working. High or low levels of electrolytes can disrupt normal bodily function.^{19,20}

Familial adenomatous polyposis (FAP): FAP is caused by a gene mutation that runs in families. In this inherited condition, abnormal growths called polyps form on the inner walls of the colon and rectum. Polyps may become cancer if they are not removed. People with FAP are at higher risk of developing desmoid tumors, often in the abdominal area.

Malignant: Cells are described as malignant when their growth is uncontrolled, with the potential to spread to other parts of the body (metastasize).

Metastasize: To spread from one area of the body to another—as when cancer cells form other tumors elsewhere in the body. For example, when cancer starts in the breast but spreads to the bones.

Progressing: When a desmoid tumor is getting worse.

Soft-tissue tumors: Tumors that form in areas such as muscle, fat, tendons, ligaments, lymph and blood vessels, nerves, or other connective tissues in the body.²¹

Systemic therapy: Treatment with medicine that travels through the bloodstream to affect cells all over the body.

*Definitions referenced to the National Cancer Institute Dictionary of Cancer Terms unless otherwise noted.

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For more information, go to
[OGSIVEO.com](https://ogsiveo.com) or call **1-888-400-7989**.

**Financial support may be available through SpringWorks
CareConnections to help you save on OGSIVEO.**

Call 844-CARES-55 (844-227-3755),
Monday – Friday 8 AM – 10 PM ET for more information.

**Please see full Prescribing Information
and Patient Information for OGSIVEO.**