

ORAL CANCER TREATMENT EDUCATION



PASSION FOR PATIENTS
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NIROGACESTAT

Name of your medication

Generic name — nirogacestat (nye-roe-GAY-se-stat)

Brand name — OGSIVEO® (og-SIH-vee-oh)

Common uses

Nirogacestat is used to treat patients with desmoid tumors.

Nirogacestat may also be used for other treatments.

Dose and schedule

Taking nirogacestat as instructed is important to allow your treatment to be as effective as possible, so here are some key points to remember.

- ☐ Your dose may vary, but the usual dose of nirogacestat is 150 milligrams (150 mg) to be taken by mouth at a scheduled time twice a day.
- ☐ Nirogacestat can be taken with or without food, but at the same time each day.
- ☐ Nirogacestat should be taken whole and not crushed, cut, or dissolved. If you are unable to swallow nirogacestat, talk to your care provider or pharmacist for possible options.
- ☐ If you miss a dose of nirogacestat, do not take an extra dose or two doses at one time. Simply take your next dose at the regularly scheduled time. Be sure to write down if you miss a dose and let your care provider know about any missed doses.

Drug and food interactions

- ☐ Nirogacestat has many drug interactions. Please inform your care providers of all prescription medications, over-the-counter medications, vitamins, and herbal products you may be taking.
- ☐ Grapefruit or grapefruit juice, Seville oranges, and starfruit may interact with nirogacestat; avoid eating or drinking these during treatment with nirogacestat.
- ☐ Avoid using acid-reducing agents such as proton pump inhibitors (e.g., omeprazole [Prilosec®], esomeprazole [Nexium®]) and histamine blockers (e.g., famotidine [Pepcid®]) while taking nirogacestat, if possible. If taken with an antacid, separate nirogacestat from the antacid by at least 2 hours.
- ☐ Talk with your care provider or pharmacist before taking new medications or supplements, or receiving any vaccines.

Storage and handling

Handle nirogacestat with care. Just like when chemotherapy is given into the vein, this drug can be toxic, and exposure of the drug to others should be limited.

- ☐ Store nirogacestat at room temperature (68°F to 77°F) in a dry location away from light.
- ☐ Keep nirogacestat out of reach of children and pets.
- ☐ Leave nirogacestat in the provided packaging until it is ready to be taken.

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- Whenever possible, you should give nirogacestat to yourself and follow the steps below. If a family member, friend, or caregiver needs to give the nirogacestat to you, they also need to follow these steps.
 1. Wash hands with soap and water.
 2. Put on gloves to avoid touching the medication. (Gloves are not necessary if you give the drug to yourself.)
 3. Gently transfer the nirogacestat from its package to a small medicine or other disposable cup.
 4. Administer the medicine immediately by mouth with water.
 5. Remove gloves and do not use them for anything else.
 6. Throw gloves and medicine cup in household trash.
 7. Wash hands with soap and water.
- If a daily pill box or pill reminder will be used, contact your care team before using.
 - The person filling the box or reminder should wear gloves (gloves are not necessary if you are filling the box or reminder).
 - When empty, the box or reminder should be washed with soap and water before refilling. Be sure to wash hands with soap and water after the task is complete, whether or not gloves are worn.

Side Effects of Nirogacestat

Below are common side effects that have been known to happen in about one-third or more of patients taking nirogacestat; these are listed on the left side of this table. You **MAY NOT** experience these side effects. Options to help manage any side effects that do occur are included on the right side of this table. These should be discussed with your care provider. If you experience any side effect you cannot manage or that is not listed here, contact your care provider.

Possible Side Effect	Management
Diarrhea	<p>Monitor how many bowel movements you have each day.</p> <ul style="list-style-type: none">• Drink 8–10 glasses of water or fluid each day unless your care provider has instructed you to limit your fluid intake.• Eat small, frequent meals throughout the day rather than a few large meals.• Eat bland, low-fiber foods (e.g., bananas, applesauce, potatoes, chicken, rice, toast).• Avoid high fiber foods, such as raw vegetables, raw fruits, and whole grains.• Avoid foods that cause gas, such as broccoli and beans.• Avoid lactose-containing foods, such as yogurt and milk.• Avoid spicy, fried, and greasy foods. <p>Contact your provider if any of the following occur:</p> <ul style="list-style-type: none">• The number of bowel movements you have in a day increases by 4 or more.• You feel dizzy or lightheaded. <p>Your care provider may recommend an over-the-counter medication called loperamide (Imodium®) to help with your diarrhea, but talk to your care provider before starting this medication.</p>

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Possible Side Effect	Management
Decreased ovarian function or changes in fertility	<p>Those who are able to become pregnant may have changes in reproductive function and fertility. Contact your care team if you notice any of the following:</p> <ul style="list-style-type: none"> • Changes in your menstrual cycle • Hot flashes • Night sweats • Vaginal dryness <p>Patients who have ovaries, have not gone through menopause, and desire future fertility should discuss these risks with your care team before starting treatment.</p>
Rash or itchy skin	<ul style="list-style-type: none"> • Keep your skin moisturized with creams and moisturizing lotions to decrease the risk of rash or itchiness, and wear loose fitting clothing. • Avoid using perfumes and cologne as these products may increase rash symptoms. • Avoid being in the heat for long periods of time. • Your provider may recommend an over-the-counter antihistamine or a topical cream. <p>Sunlight can make symptoms worse.</p> <ul style="list-style-type: none"> • Avoid sun exposure as much as possible to decrease the risk of sunburn. The highest exposure to ultraviolet (UV) radiation occurs from 10 am–4 pm. • Wear long-sleeved clothing, with UV protection if possible. • Wear broad-brimmed hats. • Apply broad-spectrum sunscreen (UVA/UVB) with at least SPF 30 as often as directed on the bottle. • Use lip balm with at least SPF 30. <p>If your rash or itching continues to worsen, contact your care provider.</p>
Fatigue	<p>You may be more tired than usual or have less energy.</p> <ul style="list-style-type: none"> • Stay as active as possible, but know it is okay to rest as needed. • Try to do some activity every day. • Plan your activities, and do them at a time of day when you feel a bit more energetic. • Stay as active as possible, but know that it is okay to rest as needed, too. • Avoid operating heavy machinery if you feel too tired.
Nausea or vomiting	<ul style="list-style-type: none"> • Eat and drink slowly. • Drink 8–10 glasses of water or fluid each day unless your care provider has instructed you to limit your fluid intake. • Eat small, frequent meals throughout the day rather than a few large meals. • Eat bland foods; avoid spicy, fried, and greasy foods. • Avoid vigorous exercise immediately after eating. • Don't lay down immediately after eating. • Avoid strong odors. <p>Let your provider know if you experience nausea or vomiting. Your provider may prescribe medication to help with the nausea or vomiting.</p>

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Possible Side Effect	Management
Mouth irritation or sores	<p>Practice good mouth care.</p> <ul style="list-style-type: none"> Rinse your mouth frequently. Brush your teeth with a soft toothbrush or cotton swab after meals. Use a mild nonalcohol mouth rinse at least 4 times a day (after eating and at bedtime). One example is a mixture of 1/8 teaspoon of salt and 1/4 teaspoon of baking soda in 8 ounces of warm (not hot) water. If you have sores in your mouth, avoid using tobacco products, alcohol, and mouthwashes that contain alcohol. <p>Call your care provider if you experience pain or sores in your mouth or throat.</p>
Headache	<p>Ask your provider what you may use to help with discomfort from headache.</p> <p>Contact your care provider right away if your headache:</p> <ul style="list-style-type: none"> Follows a head injury. Is severe or starts suddenly. Does not go away after 3 days. Is associated with vomiting, visual disturbance, neck stiffness, drowsiness, confusion, made worse by coughing or lowering the head, rash, weakness in an arm or leg, or numbness.
Changes in electrolytes and other laboratory values <ul style="list-style-type: none"> Decreased phosphate Increased urine glucose Increased urine protein Increased aspartate aminotransferase Increase alanine amino transferase 	<p>Changes in some lab values may occur and will be monitored by a simple blood test.</p> <ul style="list-style-type: none"> You may not feel any symptoms if the changes are mild, and they usually are not a sign of a serious problem. More severe changes may occur, which can be a sign of a serious problem. <p>Notify your care provider if you experience any of the following:</p> <ul style="list-style-type: none"> Shortness of breath Chest discomfort Weakness or fatigue New aches and pains Headaches Dizziness Swelling of your legs or feet Red or brown colored urine

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Serious side effects

- ☐ Nirogacestat may be harmful to your liver. Seek medical attention if you notice yellowing of the skin or whites of your eyes, dark or brown urine, bleeding, or bruising.
- ☐ Nirogacestat may increase your risk of new non-melanoma skin cancers. Check your skin and tell your care team right away about any skin changes like a new wart, sore, reddish bump that bleeds or does not heal, or change in size or color of a mole. You should perform skin self-exams and dermatological examinations prior to starting nirogacestat and routinely during treatment.

If you experience ANY uncontrolled side effect, call your physician or healthcare center immediately:

(INSTITUTIONAL CONTACT INFO)

Handling body fluids and waste

Because nirogacestat remains in your body for several days after it is taken, some of the drug may be present in urine, stool, sweat, or vomit. Once you have started to take nirogacestat, it is important to adhere to the following instructions every day for as long as your treatment lasts. This is to keep yourself, loved ones, and the environment as safe as possible.

- ☐ Pregnant women should avoid touching anything that may be soiled with body fluids from the patient.
- ☐ Toilet and septic systems:
 - You may use the same toilet, septic tank, and/or sewer that you usually use. If you have a low-flow toilet, close the lid and flush twice to ensure that all waste has been discarded.
 - If the toilet or toilet seat becomes soiled with urine, stool, or vomit, clean the surfaces before other people use the toilet.
 - Wash hands with soap and water after using the toilet.
- ☐ If you need a bedpan, be sure your caregiver knows to wear gloves to assist with cleanup and to wash the bedpan with soap and water every day.
- ☐ If you do not have good control of bladder or bowels, use a disposable pad with a plastic back, a diaper, or a sheet to absorb body waste.
- ☐ Wash any skin that has been exposed to body waste or nirogacestat with soap and water.
- ☐ Linens or clothing that are soiled with body fluids or body waste should be washed separately from other linens and clothing. If you do not have a washer, place the soiled linens in a plastic bag until they can be washed.
- ☐ Wash hands with soap and water after touching linens or clothing that may be soiled with body fluids.

Pregnancy, sexual activity, and contraception

- ☐ Women should not become pregnant and men should not get a partner pregnant while taking nirogacestat. Males and females of childbearing age and potential should use effective contraception during therapy and for a minimum of 1 week after the last dose of nirogacestat.
- ☐ Effective contraception could include 1 or more of the following: oral contraceptive, barrier methods, etc.
- ☐ Do not breastfeed while taking nirogacestat and for 1 week after the last dose of nirogacestat.
- ☐ Please inform your care provider if you become pregnant.
- ☐ It is safe to hug and kiss. Special precautions may be needed for sexual activity while on oral chemotherapy, and you are encouraged to ask your care team for assistance.

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Obtaining medication

- ☐ Talk with your care provider about the process for obtaining your nirogacestat.

(PHARMACY OR SPECIALTY PHARMACY CONTACT INFO)

Additional resources

Product website: <https://www.ogsiveo.com>

Product prescribing information: <https://springworkstx.com/wp-content/uploads/2023/11/OGSIVEO-US-Prescribing-Information-11.27.23.pdf>

Product resources: <https://springworkstxcares.com>

Updated – February 5, 2024

Additional instructions

Important notice: The Association of Community Cancer Centers (ACCC), Hematology/Oncology Pharmacy Association (HOPA), National Community Oncology Dispensing Association, Inc. (NCODA), and Oncology Nursing Society (ONS) have collaborated in gathering information for and developing this patient education guide. This guide represents a brief summary of the medication derived from information provided by the drug manufacturer and other resources. This guide does not cover all existing information related to the possible uses, directions, doses, precautions, warnings, interactions, adverse effects, or risks associated with this medication and should not substitute for the advice of a qualified healthcare professional. Provision of this guide is for informational purposes only and does not constitute or imply endorsement, recommendation, or favoring of this medication by ACCC, HOPA, NCODA, or ONS, who assume no liability for and cannot ensure the accuracy of the information presented. The collaborators are not making any representations with respect to the medications whatsoever, and any and all decisions, with respect to such medications, are at the sole risk of the individual consuming the medication. All decisions related to taking this medication should be made with the guidance and under the direction of a qualified healthcare professional.

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