

Nirogacestat (Ogsiveo)

About This Medicine

Nirogacestat is used to treat cancer. It is given orally (by mouth).

Possible Side Effects

- Soreness of the mouth and throat. You may have red areas, white patches, or sores that hurt.
- Nausea
- Diarrhea (loose bowel movements)
- Pain in your abdomen
- In women, menstrual bleeding may become irregular or stop while you are getting this medicine. Do not assume that you cannot become pregnant if you do not have a menstrual period. Women may also go through signs of menopause (change of life) like vaginal dryness or itching, night sweats and/or hot flashes.
- Tiredness
- Headache
- Electrolyte changes
- Changes in your liver function
- Increased protein in your urine, which can affect how your kidneys work
- Increased glucose in your urine
- Cough
- Upper respiratory tract infection
- Trouble breathing
- Rash
- Hair loss. Hair loss is often temporary, although with certain medicine, hair loss can sometimes be permanent. Hair loss may happen suddenly or gradually. If you lose hair, you may lose it from your head, face, armpits, pubic area, chest, and/or legs. You may also notice your hair getting thin.

Note: Each of the side effects above was reported in 15% or greater of patients treated with nirogacestat. All possible side effects are not included. Your side effects may be different depending on your cancer diagnosis, condition, or if you are receiving other medicines in combination. Please discuss any concerns or questions with your medical team.

Warnings and Precautions



- Severe diarrhea
- Severe changes in your liver function
- This medicine may raise your risk of getting non-melanoma skin cancer
- Severe decrease level of potassium and phosphate in your blood

Note: Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your medical team.

Important Information

- It is important that you notify your doctor and/or nurse at the first sign of diarrhea so they can provide you with anti-diarrheal medicine and give you further instructions. Notify your doctor and/or nurse if you are taking anti-diarrhea medicine and your symptoms have not improved or are worsening.

How to Take Your Medicine

- Swallow the medicine whole with or without food. Do not chew, break, or crush it.
- **Missed dose:** If you vomit or miss a dose, take your next dose at the regular time. Do not take 2 doses at the same time and do not double up on the next dose.
- **Handling:** Wash your hands with soap and water, before and after handling your medicine, your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- Cytotoxic medicines leave the body through urine and stool, but they can also be present in other body fluids such as blood, vomit, semen, and vaginal fluids. Take precautions to prevent others from coming in contact with your medicine or your body fluids. Follow safety precautions during your treatment and for as long as directed by your health care provider after your treatment. If you take a cytotoxic pill each day, follow these precautions every day.
- **Storage:** Store this medicine in the original container at room temperature.
- **Disposal of unused medicine:** Do not flush any expired and/or unused medicine down the toilet or drain unless you are specifically instructed to do so on the medicine label. Some facilities have take-back programs and/or other options. If you do not have a take-back program in your area, then please discuss with your nurse or your doctor how to dispose of unused medicine.

Treating Side Effects

- Drink enough fluids to keep your urine pale yellow.
- If you throw up or have diarrhea, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).
- Mouth care is very important. Your mouth care should consist of routine, gentle cleaning of your teeth or dentures and rinsing your mouth with a mixture of 1/2 teaspoon of salt in 8 ounces of water or 1/2 teaspoon of baking soda in 8 ounces of water. This should be done at least after each meal and at bedtime.
- If you have mouth sores, avoid mouthwash that has alcohol. Also avoid alcohol and smoking because they can bother your mouth and throat.



- To help with nausea and vomiting, eat small, frequent meals instead of three large meals a day. Choose foods and drinks that are at room temperature. Ask your nurse or doctor about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- If you have diarrhea, eat low-fiber foods that are high in protein and calories and avoid foods that can irritate your digestive tracts or lead to cramping.
- Ask your nurse or doctor about medicine that can lessen or stop diarrhea.
- Manage tiredness by pacing your activities for the day. Be sure to include periods of rest between energy-draining activities.
- Keeping your pain under control is important to your well-being. Please tell your doctor or nurse if you are experiencing pain.
- If you get a rash do not put anything on it unless your doctor or nurse says you may. Keep the area around the rash clean and dry. Ask your doctor for medicine if your rash bothers you.
- To help with hair loss, wash with a mild shampoo and avoid washing your hair every day. Avoid coloring your hair.
- Avoid rubbing your scalp, pat your hair or scalp dry.
- Limit your use of hair spray, electric curlers, blow dryers, and curling irons.
- If you are interested in getting a wig, talk to your nurse and they can help you get in touch with programs in your local area.

Food and Medicine Interactions

- Avoid grapefruit, grapefruit juice, Seville oranges and/or starfruit while taking this medicine as it may raise the levels of nirogacestat in your body which could make side effects worse.
- Check with your doctor or pharmacist about all other prescription medicines and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs, and others) you are taking before starting this medicine as there are known medicine interactions with nirogacestat. Also, check with your doctor or pharmacist before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.
- Medicines that treat heartburn and stomach upset may lower the effect of your cancer treatment if taken with nirogacestat. Call your doctor to find out what medicine you can take with nirogacestat to help with heartburn or stomach upset.
- This medicine may interact with St. John's Wort and may lower the levels of the medicine in your body, which can make it less effective.

When to Call the Doctor

Call your doctor or nurse if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.4° F (38° C) or higher
- Headache that does not go away
- Tiredness that interferes with your daily activities
- Wheezing and/or trouble breathing
- Cough that is bothersome and/or coughing up yellow, green, or bloody mucus
- Pain in your mouth or throat that makes it hard to eat or drink



- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Throwing up more than 3 times a day
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
- Pain in your abdomen that does not go away
- Signs of possible liver problems: dark urine, pale bowel movements, pain in your abdomen, feeling very tired and weak, unusual itching, or yellowing of the eyes or skin
- Foamy or bubbly-looking urine
- Signs of low potassium levels: weakness, tiredness, muscle cramps, constipation
- Signs of low phosphate: muscle/bone pain, weakness, tiredness, numbness/tingling, confusion
- New rash and/or itching
- Rash that is not relieved by prescribed medicines
- New skin lesions or wart
- Skin sore or reddish bump that bleeds or does not heal
- Change in size or color of a mole
- If you think you may be pregnant or may have impregnated your partner

Reproduction Warnings

- **Pregnancy warning:** This medicine can have harmful effects on the unborn baby. Women of childbearing potential should use effective methods of birth control during your cancer treatment and for 1 week after stopping treatment. Men with female partners of childbearing potential should use effective methods of birth control during your cancer treatment and for 1 week after stopping treatment. Let your doctor know right away if you think you may be pregnant or may have impregnated your partner.
- **Breastfeeding warning:** Women should not breastfeed during treatment and for 1 week after stopping treatment because this medicine could enter the breast milk and cause harm to a breastfeeding baby.
- **Fertility warning:** In men and women both, this medicine may affect your ability to have children in the future. Talk with your doctor or nurse if you plan to have children. Ask for information on sperm or egg banking.

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