

Niraparib (Zejula™)

Pronounce: Nir-a-puh-rib

Classification: PARP Inhibitor

About Niraparib (Zejula™)

Niraparib is a poly (adenosine diphosphate [ADP]-ribose) polymerase (PARP) inhibitor. Cancers related to BRCA 1 or 2 mutations seem to rely on PARP to repair damaged DNA in cancer cells, allowing them to continue to divide. By inhibiting PARP, tumor growth may be slowed or stopped.

How to Take Niraparib

Niraparib is a capsule taken by mouth once a day with or without food. Take the capsule whole. You should not open, crush, break, or chew the capsules. If you miss a dose, do not take two doses to make up for a missed dose. If you vomit after taking your dose, do not take another dose. Take the next dose at its normally scheduled time. Consult with your pharmacist or provider if you are having trouble swallowing the medication.

The capsules are 100mg each, meaning you will need to take a number of capsules to achieve the full dose. It is important to make sure you are taking the correct amount of medication every time. Before every dose, check that what you are taking matches what you have been prescribed.

This medication can affect your blood counts. These levels will be checked by a blood test before starting treatment with nirapraib and then once a week for one month and then once a month for eleven months.

Storage and Handling

Store your medication in the original, labeled container at room temperature and in a dry location (unless otherwise directed by your healthcare provider or pharmacist). This medication should not be stored in a pillbox. Keep containers out of reach of children and pets.

If a caregiver prepares your dose for you, they should consider wearing gloves or pour the pills directly from their container into the cap, a small cup, or directly into your hand. They should avoid touching the pills. They should always wash their hands before and after giving you the medication. Pregnant or nursing women should not prepare the dose for you. Ask your oncology team where to return any unused medication for disposal. Do not flush down the toilet or throw in the trash.

Where do I get this medication?

Certain cancer medications are only available through specialty pharmacies. If you need to get this medication through a specialty pharmacy, your provider will help you start this process. Where you can fill your prescriptions may also be influenced by your pharmaceutical insurance coverage. Ask your health care provider or pharmacist for assistance in identifying where you can get this medication.

Insurance Information

This medication may be covered under your prescription drug plan. Patient assistance may be available to qualifying individuals depending upon prescription drug coverage. Co-pay cards, which reduce the patient co-

pay responsibility for eligible commercially (non-government sponsored) insured patients, may also be available. Your care team can help you find these resources, if they are available.

Possible Side Effects of Niraparib

There are a number of things you can do to manage the side effects of niraparib. Talk to your care team about these recommendations. They can help you decide what will work best for you. These are some of the most common or important side effects:

Nausea and/or Vomiting

Talk to your oncology care team so they can prescribe medications to help you manage nausea and vomiting. In addition, dietary changes may help. Avoid things that may worsen the symptoms, such as heavy or greasy/fatty, spicy or acidic foods (lemons, tomatoes, oranges). Try saltines, or ginger ale to lessen symptoms.

Call your oncology care team if you are unable to keep fluids down for more than 12 hours or if you feel lightheaded or dizzy at any time.

Fatigue

Fatigue is very common during cancer treatment and is an overwhelming feeling of exhaustion that is not usually relieved by rest. While on cancer treatment, and for a period after, you may need to adjust your schedule to manage fatigue. Plan times to rest during the day and conserve energy for more important activities. Exercise can help combat fatigue; a simple daily walk with a friend can help. Talk to your healthcare team for helpful tips on dealing with this side effect.

Low Red Blood Cell Count (Anemia)

Your red blood cells are responsible for carrying oxygen to the tissues in your body. When the red cell count is low, you may feel tired or weak. You should let your doctor or nurse know if you experience any shortness of breath, difficulty breathing or pain in your chest. If the count gets too low, you may receive a blood transfusion.

Low White Blood Cell Count (Leukopenia or Neutropenia)

White blood cells (WBC) are important for fighting infection. While receiving treatment, your WBC count can drop, putting you at a higher risk of getting an infection. You should let your doctor or nurse know right away if you have a fever (temperature greater than 100.4°F or 38°C), sore throat or cold, shortness of breath, cough, burning with urination, or a sore that doesn't heal.

Tips to preventing infection:

- Washing hands, both yours and your visitors, is the best way to prevent the spread of infection.
- Avoid large crowds and people who are sick (i.e.: those who have a cold, fever or cough or live with someone with these symptoms).
- When working in your yard, wear protective clothing including long pants and gloves.
- Do not handle pet waste.
- Keep all cuts or scratches clean.
- Shower or bathe daily and perform frequent mouth care.
- Do not cut cuticles or ingrown nails. You may wear nail polish, but not fake nails.
- Ask your care team before scheduling dental appointments or procedures.
- Ask your care team before you, or someone you live with, has any vaccinations.

Low Platelet Count (Thrombocytopenia)

Platelets help your blood clot, so when the count is low you are at a higher risk of bleeding. Let your doctor or

nurse know if you have any excess bruising or bleeding, including nose bleeds, bleeding gums or blood in your urine or stool. If the platelet count becomes too low, you may receive a transfusion of platelets.

- Do not use a razor (an electric razor is fine).
- Avoid contact sports and activities that can result in injury or bleeding.
- Do not take aspirin (salicylic acid), non-steroidal, anti-inflammatory medications (NSAIDs) such as Motrin®, Aleve®, Advil®, etc. as these can all increase the risk of bleeding. Unless your healthcare team tells you otherwise, you may take acetaminophen (Tylenol).
- Do not floss or use toothpicks and use a soft-bristle toothbrush to brush your teeth.

High Blood Sugar

This medication can cause higher levels of blood sugar in patients with and without diabetes. Your oncology care team will monitor your blood sugar. If you develop increased thirst, urination or hunger, blurry vision, headaches or your breath smells like fruit, notify your healthcare team. Diabetics should monitor their blood sugar closely and report elevations to the healthcare team.

Constipation

There are several things you can do to prevent or relieve constipation. Include fiber in your diet (fruits and vegetables), drink 8-10 glasses of non-alcoholic fluids a day, and keep active. A stool softener once or twice a day may prevent constipation. If you do not have a bowel movement for 2 to 3 days, you should contact your healthcare team for suggestions to relieve the constipation.

Liver Toxicity

This medication can cause liver toxicity, which your oncology care team may monitor for using blood tests called liver function tests. Notify your healthcare provider if you notice yellowing of the skin or eyes, your urine appears dark or brown, or you have pain in your abdomen, as these can be signs of liver toxicity.

Muscle or Joint Pain/Aches and Headache

Your healthcare provider can recommend medications and other strategies to help relieve pain.

Electrolyte Abnormalities

This medication can affect the normal levels of electrolytes (magnesium, calcium, etc.) in your body. Your levels will be monitored using blood tests. If your levels become too low, your care team may prescribe specific electrolytes to be given by IV or taken by mouth. Do not take any supplements without first consulting with your care team.

Kidney Toxicity

This medication can cause kidney toxicity, which your oncology team will monitor for using blood tests to check your creatinine level. Notify your care team if you notice decreased urine output, dark colored urine, blood in the urine, or swelling in the ankles.

Insomnia

Insomnia is a change in sleep and can include not being able to sleep or difficulty falling or staying asleep. This medication can cause or worsen pre-existing insomnia. Inform your healthcare provider if you are experiencing changes in your sleep.

Important but Less Common Side Effects

• **Heart Problems/High Blood Pressure**: This medication can cause high blood pressure and heart palpitations. Your blood pressure and heart rate will be monitored often. If you have symptoms such as headache, dizziness, feeling like your heart is racing, skipping a beat or fluttering, call your care team

right away.

- **Secondary Cancers:** A secondary cancer is one that develops as a result of cancer treatment for another cancer. This is quite rare, but you should be aware of the risk. In most cases, a secondary cancer related to chemotherapy is a blood cancer (MDS, leukemia, lymphoma). This can occur years after treatment. This is most often associated with repeated treatments or high doses. Your provider will monitor your labs closely. Consider having a complete blood count with differential checked annually by your healthcare provider if you received high risk therapies.
- **Posterior Reversible Encephalopathy Syndrome (PRES):** PRES is a rare, reversible neurological disorder that can occur with the use of niraparib. Symptoms of PRES include seizure, high blood pressure, headache, confusion, fatigue, confusion, any changes in your vision, or having a hard time walking or thinking. If you have any of these symptoms, call your care team or go to the emergency room right away.

Sexual and Reproductive Concerns

This medication may affect men's reproductive system, resulting in sperm production becoming irregular or stopping permanently. The desire for sex may decrease during treatment. You may want to consider sperm banking if you may wish to have a child in the future. Discuss these options with your oncology team.

Exposure of an unborn child to this medication could cause birth defects, so you should not become pregnant while on this medication. Effective birth control is necessary during treatment and for at least 6 months after treatment. Even if your menstrual cycle stops, you could still be fertile and conceive. You should not breastfeed while taking this medication or for one month after your last dose.

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