

Niraparib and Abiraterone acetate (Akeega)

About This Medicine

NIRAPARIB; ABIRATERONE (nye RAP a rib; A bir A ter one) treats prostate cancer. It works by decreasing levels of the hormone testosterone in the body. It also blocks a protein that causes cancer cells to grow and multiply. This prevents prostate cancer cells from spreading or growing. It is given orally (by mouth).

This medicine may be used for other purposes; ask your care team if you have questions.

Possible Side Effects

- Bone marrow suppression. This is a decrease in the number of white blood cells, red blood cells, and platelets. This may raise your risk of infection, make you tired and weak, and raise your risk of bleeding.
- Abnormal heartbeat
- Nausea and vomiting (throwing up)
- Pain in your abdomen
- Constipation (not able to move bowels)
- Tiredness
- Swelling of the hands, feet, or any other part of the body
- Abnormal bleeding – symptoms may be coughing up blood, throwing up blood (may look like coffee grounds), red or black tarry bowel movements, abnormally heavy menstrual flow, nosebleeds, or any other unusual bleeding.
- Fever
- Changes in your liver function
- Decreased appetite (decreased hunger)
- Weight loss
- Electrolyte changes
- COVID-19 infection
- Muscle and bone pain
- Risk of fall
- Headache
- Trouble sleeping
- Feeling dizzy
- Changes in your kidney function

- Urinary tract infection
- Cough
- Trouble breathing
- High blood pressure

Note: Each of the side effects above was reported in 10% or greater of people treated with niraparib and abiraterone acetate. 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 drugs in combination. Please discuss any concerns or questions with your care team.

Warnings and Precautions

- Severe bone marrow suppression
- Severe low potassium, high blood pressure, and swelling, which can cause abnormal electrocardiogram (EKG/ECG) and abnormal heartbeats.
- Changes in your adrenal gland function
- Severe changes in your liver function, which can cause liver failure and be life-threatening.
- Increased risk of bone fracture and death when niraparib and abiraterone acetate and prednisone are used in combination with radium Ra 223 dichloride.
- Increased risk of low blood sugar in people taking certain types of medicines that treat type 2 diabetes mellitus.
- This medicine may raise your risk of getting a second cancer, such as myelodysplastic syndrome and acute myeloid leukemia, which can be life-threatening.
- Swelling in the brain that is usually reversible. Symptoms can be sudden (acute) and may include a headache, confusion, changes in eyesight, extreme tiredness/coma, and/or seizures. **If you start to have any of these symptoms let your care team know right away.**

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

Important information

- Niraparib and abiraterone acetate is usually taken in combination with prednisone. Some people may also be taking a GnRH analog medicine. Follow your care team's instructions for how to take your medicines. Do not stop taking your medicines without consulting your care team.

How to Take Your Medicine

- Swallow this medicine whole with water on an empty stomach. Do not eat food 2 hours before or 1 hour after taking this medicine. Do not break, crush or chew tablets.
- **Missed dose:** If you miss a dose, take it as soon as possible on the same day. Return to your normal schedule on the following day. Do not take 2 doses at the same time and do not double up on the next dose.



- **Overdosage:** If you think you have taken too much of this medicine contact a poison control center or emergency room at once.
- **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.
- Pregnant people or people trying to become pregnant should not handle niraparib and abiraterone acetate without using protection such as gloves.
- This medicine may be present in the urine, stool and 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 care team after your treatment. If you take a pill each day, follow these precautions every day.
- **Storage:** Store this medicine in the original container at room temperature. Keep out of the reach of children and pets.
- **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 care team how to dispose of unused medicine.

Treating Side Effects

- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities.
- If you are dizzy, get up slowly after sitting or lying.
- Get regular exercise, with your care team's approval. If you feel too tired to exercise vigorously, try taking a short walk.
- To decrease the risk of infection, wash your hands regularly.
- Avoid close contact with people who have a cold, the flu, or other infections.
- Take your temperature as your care team tells you, and whenever you feel like you may have a fever.
- To help decrease the risk of bleeding, use a soft toothbrush. Check with your care team before using dental floss.
- Be very careful when using knives or tools.
- Use an electric shaver instead of a razor.
- Drink enough fluids to keep your urine pale yellow.
- If you throw up, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).
- 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 care team about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- If you are not able to move your bowels, check with your care team before you use enemas, laxatives, or suppositories.
- Ask your care team about medicines that are available to help stop or lessen constipation.
- To help with weight loss, drink fluids that contribute calories (whole milk, juice, soft drinks, sweetened beverages, milkshakes, and nutritional supplements) instead of water.
- Include a source of protein at every meal and snack, such as meat, poultry, fish, dry beans, tofu, eggs, nuts, milk, yogurt, cheese, ice cream, pudding, and nutritional supplements.



- To help with decreased appetite, eat small, frequent meals. Eat foods high in calories and protein, such as meat, poultry, fish, dry beans, tofu, eggs, nuts, milk, yogurt, cheese, ice cream, pudding, and nutritional supplements.
- Consider using sauces and spices to increase taste. Daily exercise, with your care team's approval, may increase your appetite.
- If you have diabetes, keep good control of your blood sugar level. Tell your care team if your glucose levels are higher or lower than normal.
- Keeping your pain under control is important to your well-being. Please tell your care team if you are experiencing pain.

Food and Medicine Interactions

- Niraparib and abiraterone acetate should be taken on an empty stomach.
- Check with your care team 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 niraparib and abiraterone acetate. Also, check with your care team before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.
- 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.
- There are known interactions of niraparib and abiraterone acetate with some medicines that treat type 2 diabetes mellitus. Ask your care team what precautions you should take.

When to Call Your Care Team

Call your care team if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.4° F (38° C) or higher
- Chills
- Confusion
- Extreme tiredness and/or coma
- Tiredness and/or extreme weakness that interferes with your daily activities
- Feeling dizzy or lightheaded
- Trouble falling or staying asleep
- Blurry vision or other changes in eyesight
- Headache that does not go away
- Symptoms of a seizure such as confusion, blacking out, passing out, loss of hearing or vision, blurred vision, unusual smells or tastes (such as burning rubber), trouble talking, tremors or shaking in parts or all of the body, repeated body movements, tense muscles that do not relax, and loss of control of urine and bowels. **If you or your family member suspects you are having a seizure, call 911 right away.**
- Feeling that your heart is beating fast or in a not normal way (palpitations)
- Cough that is bothersome
- Wheezing and/or trouble breathing



- New loss of taste or smell
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Throwing up more than 3 times a day
- No bowel movement in 3 days or when you feel uncomfortable
- Pain in your abdomen that does not go away
- Lasting loss of appetite or rapid weight loss of five pounds in a week
- Signs of abnormal bleeding such as coughing up blood, throwing up blood (may look like coffee grounds), easy bleeding or bruising, red or black tarry bowel movements, abnormally heavy menstrual flow, nosebleeds, or any other unusual bleeding
- 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
- Signs of possible low potassium levels: weakness, tiredness, muscle cramps, constipation
- Abnormal blood sugar
- Signs of low blood sugar: feeling sleepy, increased hunger, sweating, shakiness, irritability
- Signs of low adrenal gland function: nausea, vomiting (throwing up), loss of appetite, tiredness, weakness, feeling dizzy or lightheaded)
- Signs of a urinary tract infection such as burning or pain when you pass urine, trouble urinating, smelly and/or cloudy urine, pain in your lower abdomen or lower/side of your back.
- Weight gain of 5 pounds in one week (fluid retention)
- Swelling of the hands, feet, or any other part of the body
- Pain that does not go away or is not relieved by prescribed medicines
- Experience a fall
- Decreased or very dark urine

Reproduction Warnings

- **Pregnancy warning:** This medicine can cause serious birth defects. If you can get your partner pregnant, use birth control while taking this medicine and for 4 months after the last dose. Tell your care team right away if you think your partner might be pregnant.
- **Fertility warning:** This medicine may affect your ability to have children in the future. If you plan to have children, talk with your care team.

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