

Niraparib and Abiraterone acetate (Akeega)

About This Medicine

Niraparib and abiraterone acetate is used to treat cancer. It is given orally (by mouth).

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 patients 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 medical 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 patients 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 doctor 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 medical team.

Important information

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

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.
- **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.
- Women that are pregnant or are trying to become pregnant should not handle niraparib and abiraterone acetate without protection such as 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

- 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 doctor'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 doctor or nurse 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 nurse 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 nurse or doctor 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 doctor or nurse before you use enemas, laxatives, or suppositories.
- Ask your doctor or nurse 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 doctor's approval, may increase your appetite.



- If you have diabetes, keep good control of your blood sugar level. Tell your nurse or your doctor if your glucose levels are higher or lower than normal.
- Keeping your pain under control is important to your well-being. Please tell your doctor or nurse if you are experiencing pain.

Food and Medicine Interactions

- Niraparib and abiraterone acetate should be taken on an empty stomach.
- 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 niraparib and abiraterone acetate. 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.
- 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 doctor what precautions you should take.

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
- 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, difficulty 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
- If you think you may have impregnated your partner

Reproduction Warnings

- **Pregnancy warning:** This medicine can have harmful effects on an unborn baby and cause loss of pregnancy. Niraparib and abiraterone acetate is not indicated for use in women. Men with female partners of childbearing potential should use effective methods of birth control during your cancer treatment and for 4 months after stopping treatment. Let your doctor know right away if you think you may have impregnated your partner.
- **Breastfeeding warning:** It is not known if this medicine passes into breast milk. Niraparib and abiraterone acetate is not indicated for use in women.
- **Fertility warning:** In men, 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 banking.

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