

ORAL CANCER TREATMENT EDUCATION



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NIRAPARIB AND ABIRATERONE

Name of your medication

Generic name — niraparib (nih-RA-puh-rib) / abiraterone acetate (A-bih-RA-tehrone A-seh-tayt)

Brand name — AKEEGA® (uh-KEE-guh)

Common uses

The combination of niraparib/abiraterone acetate is used to treat prostate cancer that has a variant in the *BRCA* genes.

Niraparib/abiraterone acetate may also be used for other treatments.

Dose and schedule

Taking niraparib/abiraterone acetate 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 niraparib/abiraterone acetate is 2 tablets (200 milligrams niraparib and 1000 milligrams abiraterone) to be taken by mouth at a scheduled time once daily in combination with prednisone (10 milligrams) daily.
- ❑ Niraparib/abiraterone acetate should be taken on an empty stomach. Take niraparib/abiraterone acetate 1 hour before or at least 2 hours after a meal.
- ❑ Niraparib/abiraterone acetate should be taken whole and not crushed, cut, or dissolved. If you are unable to swallow niraparib/abiraterone acetate, talk to your care provider or pharmacist for possible options.
- ❑ When taking niraparib/abiraterone acetate, **do not** take two doses at one time, be sure to write down if you miss a dose, and let your care provider know about any missed doses.
- ❑ Do not take an additional dose of either medication if vomiting occurs after administration. Continue with the next scheduled dose.

Drug and food interactions

- ❑ Niraparib/abiraterone acetate have many drug interactions. Inform your care providers of all prescription medications, over-the-counter medications, vitamins, and herbal products that you are taking.
- ❑ Niraparib/abiraterone acetate should be taken without food (administer abiraterone and niraparib at least 1 hour before or at least 2 hours after eating).
- ❑ Talk with your care provider or pharmacist before taking new medications or supplements, or before receiving any vaccines.

ORAL CANCER TREATMENT EDUCATION



NIRAPARIB AND ABIRATERONE

Storage and handling

Handle niraparib/abiraterone acetate 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 niraparib/abiraterone acetate at room temperature (68°F to 77°F) in a dry location away from light.
- ❑ Keep niraparib/abiraterone acetate out of reach of children and pets.
- ❑ Leave niraparib/abiraterone acetate in the provided packaging until it is ready to be taken.
- ❑ Whenever possible, you should give niraparib/abiraterone acetate to yourself and follow the steps below. If a family member, friend, or caregiver needs to give the niraparib/abiraterone acetate 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 niraparib/abiraterone acetate from its package to a small medicine cup 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, and follow these guidelines:
 - The person filling the pill box or pill reminder should wear gloves (gloves are not necessary if you are filling the box or reminder).
 - When empty, the pill box or pill 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.
- ❑ If you have any unused niraparib/abiraterone acetate, **do not** throw it in the trash and **do not** flush it down the sink or toilet. Talk to your care provider or pharmacist about proper disposal of niraparib/abiraterone acetate.
- ❑ If you are traveling, put your niraparib/abiraterone acetate in a separate sealed plastic bag. Ask your pharmacist if any additional travel precautions are needed.

ORAL CANCER TREATMENT EDUCATION



NIRAPARIB AND ABIRATERONE

Side Effects of Niraparib/Abiraterone Acetate

Below are common side effects that have been known to happen in about one-third or more of patients taking niraparib/abiraterone acetate; 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
<p>Decreased hemoglobin, part of the red blood cells that carry iron and oxygen</p>	<p>Your hemoglobin should be monitored using a blood test. When your hemoglobin is low, you may notice that you get tired or fatigued more easily.</p> <ul style="list-style-type: none"> • Try to get 7–8 hours of sleep per night. • Avoid operating heavy machinery if you feel too tired. • Find a balance between “work” and “rest.” • Stay as active as possible, but know that it is okay to rest as needed, too. • You might notice that you are more pale than usual. <p>Let your care provider know right away if you experience the following symptoms:</p> <ul style="list-style-type: none"> • Shortness of breath • Dizziness • Palpitations
<p>Decreased white blood cells (WBCs) and increased risk for infection</p>	<p>Your WBCs should be monitored by a simple blood test. When your WBCs are low, you are at a greater risk of having an infection. Take the following precautions to protect yourself from infection.</p> <ul style="list-style-type: none"> • Wash your hands often, especially before eating and after using the bathroom. • Avoid crowds and people with fevers, flu, or other infections. • Bathe regularly to keep good personal hygiene. <p>Contact your care provider if you experience any of the following signs or symptoms of an infection:</p> <ul style="list-style-type: none"> • Fever (temperature more than 100.4°F or 38°C) • Chills • Sore throat • Burning with urination • Unusual tiredness • A sore that becomes red, is draining, or does not heal <p>Check with your care provider before taking any medicine for a fever or chills.</p>

Continued on the next page

ORAL CANCER TREATMENT EDUCATION



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NIRAPARIB AND ABIRATERONE

Possible Side Effect	Management
<p>Muscle or joint pain or weakness</p>	<p>Keep a diary of your pain, including a description of when and where the pain is occurring, what it feels like, and how long it lasts. Take the following precautions:</p> <ul style="list-style-type: none"> • Stay as active as possible, but know that it is OK to rest as needed, too. • Tell your care provider if pain interferes with your activity. <p>If the pain or weakness bothers you, ask your provider what you may use to help with this discomfort. Take only pain medication that has been prescribed or recommended by your care provider.</p>
<p>Fatigue</p>	<p>You may be more tired than usual or have less energy. Take the following precautions:</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.
<p>Decreased platelet count and increased risk of bleeding</p>	<p>Your platelets should be monitored by a simple blood test. When they are low, you may bruise or bleed more easily than usual. Take the following precautions:</p> <ul style="list-style-type: none"> • Use caution to avoid bruises, cuts, or burns. • Blow your nose gently and do not pick your nose. • Brush your teeth gently with a soft toothbrush and maintain good oral hygiene. • When shaving, use an electronic razor instead of razor blades. • Use a nail file instead of nail clippers. <p>Call your care provider if you have bleeding that won't stop. Examples include:</p> <ul style="list-style-type: none"> • A bloody nose that bleeds for more than five minutes despite pressure • A cut that continues to ooze despite pressure • Gums that bleed excessively when you floss or brush <p>Seek medical help immediately if you experience any severe headaches, blood in your urine or stool, blood when you cough, or prolonged and uncontrollable bleeding.</p> <p>You may need to take a break or "hold" your medication for medical or dental procedures. Talk to your care provider or dentist before any scheduled procedures.</p>

Continued on the next page

ORAL CANCER TREATMENT EDUCATION



NIRAPARIB AND ABIRATERONE

Possible Side Effect	Management
<p>Constipation</p>	<p>Monitor how many bowel movements you have each day. Take the following precautions:</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. • Stay active and exercise, if possible. • Eat foods high in fiber like raw fruits and vegetables. <p>Contact your care provider if you have not had a bowel movement in 3 or more days. Your care provider may recommend over-the-counter medications to help with your constipation. A daily stool softener such as docusate (Colace®) and/or a laxative such as senna (Senokot®) may be helpful. If these do not help within 48 hours, tell your provider.</p>
<p>Increased blood pressure</p>	<p>Routinely take your blood pressure. Record your blood pressure in a journal or diary, and report your findings to your physician. Contact your healthcare provider if you have high blood pressure or if the following or similar symptoms occur:</p> <ul style="list-style-type: none"> • Headache • Dizziness • Chest pain • Shortness of breath • Fluid retention, weight gain, or swelling
<p>Changes in liver function</p>	<p>Your liver function will be checked periodically by a simple blood test. Contact your care provider if you notice any of the following symptoms:</p> <ul style="list-style-type: none"> • Yellowing of the skin or whites of your eyes • Dark or brown urine • Bleeding or bruising
<p>Nausea or vomiting</p>	<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 that can help.</p>

Continued on the next page

ORAL CANCER TREATMENT EDUCATION



PASSION FOR PATIENTS
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NIRAPARIB AND ABIRATERONE

Possible Side Effect	Management
Changes in electrolytes and other laboratory values <ul style="list-style-type: none">• Increased serum creatinine• Increased or decreased potassium• Decreased blood sugar	<p>Changes in some laboratory 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• Headaches• Dizziness• Increased thirst or hunger• Increased urination

Serious side effects

- ❑ Niraparib/abiraterone acetate may increase your risk for certain blood cancers. Be sure to alert your physician if you notice any abnormal bruising or bleeding.
- ❑ There is a low risk that you may develop a rare condition called posterior reversible leukoencephalopathy syndrome (PRES) while taking niraparib/abiraterone acetate. Seek care immediately if you have severe headaches, seizures, confusion, or changes in vision.
- ❑ Niraparib/abiraterone acetate can alter your body's ability to make the right amount of steroids. Tell your healthcare provider if you have any of the following symptoms: dizziness, fast heartbeat, feelings of being faint or lightheaded, headache, confusion, muscle weakness, pain in your legs, or swelling in your legs or feet.
- ❑ Niraparib/abiraterone acetate may be harmful to your adrenal glands. Speak to your care provider to know when you need to have laboratory tests done to monitor your adrenal glands. Steroid medication is often prescribed to help with this side effect.
- ❑ Niraparib/abiraterone acetate may be harmful to your liver. Speak to your care provider to know when you need to have laboratory tests done to monitor your liver function. If you experience this side effect, your doctor may change your dosage or stop treatment for some time.

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

(INSTITUTIONAL CONTACT INFO)

ORAL CANCER TREATMENT EDUCATION



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NIRAPARIB AND ABIRATERONE

Handling body fluids and waste

Because niraparib/abiraterone acetate 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 niraparib/abiraterone acetate, 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 niraparib/abiraterone acetate 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 washing machine, 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

- Niraparib/abiraterone acetate is not for use by women. Men should not get a partner pregnant while taking niraparib/abiraterone acetate.
- Males with female partners of childbearing age and potential should use effective contraception during therapy and for a minimum of 4 months after the last dose of niraparib/abiraterone acetate.
- It is safe to hug and kiss. Special precautions may be needed for sexual activity while taking oral chemotherapy, and you are encouraged to ask your care team for assistance.

Obtaining medication

- Talk with your care provider about the process for obtaining your niraparib/abiraterone acetate.

(PHARMACY OR SPECIALTY PHARMACY CONTACT INFO)

ORAL CANCER TREATMENT EDUCATION



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NIRAPARIB AND ABIRATERONE

Additional resources

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

Product prescribing information:

<https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/AKEEGA-pi.pdf>

Product resources: <https://www.akeega.com/patient-resources>

Updated – November 10, 2023

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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