



ONCE-DAILY
Akeega[™]
(niraparib/abiraterone acetate)
100mg/500mg tablets • 50mg/500mg tablets



Starting treatment for *BRCA*-mutated mCRPC

This guide will walk you through what to expect when starting treatment with AKEEGA[™].

AKEEGA[™] is FDA-approved with prednisone for adults with metastatic castration-resistant prostate cancer (mCRPC) who have *BRCA1* or *BRCA2* genetic mutations.

What is AKEEGA[™] (niraparib and abiraterone acetate)?

AKEEGA[™] is a prescription medicine used with prednisone to treat adults with prostate cancer:

- who have a certain type of abnormal *BRCA* gene, and
- whose prostate cancer has spread to other parts of the body and no longer responds to medical or surgical treatment that lowers testosterone (metastatic castration-resistant prostate cancer).

Your healthcare provider will perform a test to make sure AKEEGA[™] is right for you.

It is not known if AKEEGA[™] is safe and effective in females.

It is not known if AKEEGA[™] is safe and effective in children.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about AKEEGA[™]?

AKEEGA[™] may cause serious side effects including:

- Bone marrow problems called myelodysplastic syndrome (MDS) or a type of cancer of the blood called acute myeloid leukemia (AML). MDS or AML that may lead to death has happened in people treated with niraparib, one of the medicines in AKEEGA[™]. If you develop MDS or AML, your healthcare provider will stop treatment with AKEEGA[™].

Please see Important Safety Information throughout.

Please see the full [Prescribing Information](#) for AKEEGA[™].

What is AKEEGA™?

AKEEGA™ is a combination treatment used with prednisone for adults with *BRCA*+ mCRPC, or prostate cancer that has spread to other areas and does not respond to hormone treatments that you may have taken in the past.



BRCA1/2 are genes that, when mutated, can change how your cancer develops and how it reacts to treatment.

How does the dual action tablet work?

AKEEGA™ combines 2 types of medicine:

Niraparib

is a **PARP** inhibitor, a type of **targeted therapy** that helps prevent cancer cells from multiplying in patients with *BRCA1/2* mutations



Abiraterone Acetate

stops your body from making androgens, such as testosterone; this can slow the growth of prostate cancer

IMPORTANT SAFETY INFORMATION (CONT'D)

AKEEGA™ may cause serious side effects including (cont'd):

Symptoms of low blood cell counts (low red blood cells, low white blood cells, and low platelets) are common during treatment with AKEEGA™ but can also be a sign of serious bone marrow problems, including MDS and AML. Tell your healthcare provider if you have any of the following symptoms during treatment with AKEEGA™:

- pale skin
- weakness
- shortness of breath
- feeling tired
- bruising or bleeding more easily
- fever
- frequent infections
- blood in urine or stool
- weight loss

Please see Important Safety Information throughout.

2 Please see the full [Prescribing Information](#) for AKEEGA™.

How can AKEEGA™ help me?

AKEEGA™ was studied in a clinical trial of 423 men with your specific type of cancer, mCRPC. Over half of them were positive for *BRCA* gene mutations.



AKEEGA™ with prednisone was shown to slow prostate cancer from getting worse in patients with *BRCA* mutations.



Talk to your doctor about how AKEEGA™ may help keep your cancer from worsening.

Learn more at [AKEEGA.com](https://www.akeega.com)

Did you know?

- **Poly (ADP-ribose) polymerase (PARP)** is a type of protein that helps repair DNA within cells
- **Targeted therapy** is a type of treatment that uses drugs or other substances to target specific molecules that cancer cells need to survive and spread

IMPORTANT SAFETY INFORMATION (CONT'D)

AKEEGA™ may cause serious side effects including (cont'd):

Your healthcare provider will do blood tests to check your blood cell counts:

- weekly during the first month of treatment,
- every 2 weeks for the next 2 months of treatment,
- monthly for the remainder of the year,
- then every other month and as needed during treatment with AKEEGA™.

See “What are the possible side effects of AKEEGA™?” for more information about side effects.

Please read Important Safety Information throughout.

Please see the full [Prescribing Information](#) for AKEEGA™.



How should I take AKEEGA™?



AKEEGA™ is the only FDA-approved combination treatment for *BRCA+* mCRPC available in a single, dual action tablet

Take AKEEGA™ tablets daily* on an empty stomach

2 TABLETS WITH WATER



ONCE DAILY



EMPTY STOMACH



*AKEEGA™ is indicated with prednisone.



Take AKEEGA™ and prednisone exactly as your healthcare provider tells you



Do not eat food for 2 hours before and 1 hour after taking AKEEGA™. Taking AKEEGA™ with food may cause more of the medicine to be absorbed by the body than is needed, and this may cause side effects



Swallow AKEEGA™ tablets whole with water. Do not break, crush, or chew tablets



If you miss a dose of AKEEGA™, take it as soon as possible that day and return to normal schedule the next day



AKEEGA™ can be taken first thing in the morning or before bedtime to fit your schedule

IMPORTANT SAFETY INFORMATION (CONT'D)

Before taking AKEEGA™, tell your healthcare provider about all of your medical conditions, including if you:

- have high blood pressure or heart problems
- have low blood potassium levels
- have liver or kidney problems
- have a history of adrenal problems
- have diabetes
- are receiving any other treatment for prostate cancer
- are pregnant or plan to become pregnant. AKEEGA™ can cause harm to your unborn baby and loss of pregnancy (miscarriage). Females who are or may become pregnant should handle AKEEGA™ tablets with protection, such as gloves.

Please see Important Safety Information throughout.

4 Please see the full [Prescribing Information](#) for AKEEGA™.

How will my doctor monitor for potential side effects?

When starting any new treatment, monitoring is important.

Once you begin treatment with AKEEGA™, your doctor or nurse will check your blood pressure, do blood tests, and check for other signs and symptoms of side effects.



You can expect blood tests and blood pressure checks at the beginning of therapy and throughout your treatment.



of people remained on AKEEGA™ without discontinuing treatment due to side effects



of people taking AKEEGA™ did not need a dose reduction due to side effects



of people with *BRCA+* mCRPC remained on AKEEGA™ without interruption due to side effects

It's important to talk to your doctor about any side effects you experience.

IMPORTANT SAFETY INFORMATION (CONT'D)

Before taking AKEEGA™, tell your healthcare provider about all of your medical conditions, including if you (cont'd):

- have a partner who is pregnant or may become pregnant. Males with female partners who are able to become pregnant should use effective birth control (contraception) during treatment and for 4 months after the last dose of AKEEGA™.
- are breastfeeding or plan to breastfeed. It is not known if AKEEGA™ passes into your breastmilk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. AKEEGA™ may affect the way other medicines work, and other medicines may affect how AKEEGA™ works.

Please read Important Safety Information throughout.

Please see the full [Prescribing Information](#) for AKEEGA™.



IMPORTANT SAFETY INFORMATION (CONT'D)

How should I take AKEEGA™?

- Take AKEEGA™ and prednisone exactly as your healthcare provider tells you.
- Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with AKEEGA™ if you have certain side effects.
- **Do not change or stop taking your prescribed dose of AKEEGA™ or prednisone without talking with your healthcare provider first.**
- Take your prescribed dose of AKEEGA™ 1 time a day.
- Take AKEEGA™ on an **empty stomach. Do not eat food 2 hours before and 1 hour after taking AKEEGA™.** Taking AKEEGA™ with food may cause more of the medicine to be absorbed by the body than is needed and this may cause side effects.
- Swallow AKEEGA™ tablets whole with water. Do not break, crush, or chew tablets.
- If you miss a dose of AKEEGA™, take the dose as soon as possible on the same day. Return to your normal schedule on the following day. Do not take extra tablets to make up the missed dose.
- You should start or continue a gonadotropin-releasing hormone (GnRH) analog therapy during your treatment with AKEEGA™ unless you have had a surgery to lower the amount of testosterone in your body (surgical castration).
- If you take too much AKEEGA™, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of AKEEGA™?

AKEEGA™ may cause serious side effects, including:

- See “What is the most important information I should know about AKEEGA™?”
- **Low blood potassium levels (hypokalemia), fluid retention (edema), high blood pressure (hypertension) and heart problems.** To decrease the chance of this happening, you must take prednisone with AKEEGA™ exactly as your healthcare provider tells you. Your healthcare provider will check your blood pressure, do blood tests to check your potassium levels, and check for any signs and symptoms of fluid retention at least weekly for the first 2 months of treatment, then 1 time a month during treatment with AKEEGA™. Tell your healthcare provider if you have any of the following symptoms:
 - dizziness
 - fast or irregular heartbeats
 - feel faint or lightheaded
 - headache
 - confusion
 - muscle weakness
 - pain in your legs
 - swelling in your hands, ankles, legs or feet
- **Liver problems.** Severe liver problems, liver failure and death has happened in people treated with abiraterone acetate, one of the medicines in AKEEGA™. Your healthcare provider will do blood tests to check your liver function before starting treatment with AKEEGA™, every 2 weeks for the first 3 months of treatment, and then monthly thereafter during treatment with AKEEGA™. Tell your

Please see Important Safety Information throughout.

6 Please see the full [Prescribing Information](#) for AKEEGA™.

healthcare provider right away if you develop any symptoms of liver problems, including:

- yellowing of the skin or eyes
 - darkening of the urine
 - severe nausea or vomiting
- **Adrenal problems.** Adrenal problems may happen if you stop taking prednisone, get an infection, or are under stress. Tell your healthcare provider right away if you develop any symptoms of adrenal problems, including:
- feeling tired
 - weakness
 - feeling dizzy or lightheaded
 - nausea or vomiting
 - weight loss
- **Low blood sugar (hypoglycemia).** AKEEGA™ may cause low blood sugar in people taking medicines for diabetes. Severe low blood sugar has happened in people who take certain medicines for diabetes and were treated with abiraterone acetate, one of the medicines in AKEEGA™. You and your healthcare provider should check your blood sugar levels during treatment and after you stop treatment with AKEEGA™. Your healthcare provider may need to change the dose of your diabetes medicine to decrease your risk of low blood sugar. Tell your healthcare provider right away if you have any of the following signs or symptoms of low blood sugar, including:
- headache
 - drowsiness
 - weakness
 - dizziness
 - confusion
 - irritability
 - hunger
 - fast heartbeat
 - sweating
 - feeling jittery
- **Increased risk of bone fracture and death** when abiraterone acetate, one of the medicines in AKEEGA™, and prednisone or prednisolone is used in combination with a type of radiation called Radium 223 (Ra-223) dichloride. You should not receive treatment with Ra-223 dichloride for at least 5 days after your last dose of AKEEGA™ with prednisone. Tell your healthcare provider about any other treatments you are taking for prostate cancer.
- **Posterior Reversible Encephalopathy Syndrome (PRES).** PRES is a condition that affects the brain and may happen during treatment with AKEEGA™. If you have headache, vision changes, confusion, or seizure with or without high blood pressure, please contact your healthcare provider.

The most common side effects of AKEEGA™ include:

- muscle and bone pain
- tiredness
- changes in liver function blood tests
- constipation
- high blood pressure
- nausea
- changes in kidney function blood tests
- increased potassium level in the blood
- decreased potassium level in the blood
- swelling in your legs or feet
- shortness of breath
- decreased appetite
- vomiting
- dizziness
- Coronavirus disease 2019 (COVID-19)

Please see the full [Prescribing Information for AKEEGA™](#).



Finding additional support in navigating your AKEEGA™ treatment journey is one step away

Easy-to-access resources to help you get started and stay on track with your treatment.



Explore options that may help you pay for your medication.



Learn about your cancer, your Janssen medication, and other resources to support your practical and emotional needs during your cancer treatment journey.



Connect 1-on-1 with a **Care Navigator** at **844-628-1234**, Monday through Friday, 8:30 AM–8:30 PM ET.

- A Care Navigator can help simplify and personalize your support throughout your treatment journey. Spanish-speaking Care Navigators are available.

Connect with a Care Navigator today

Sign up online to have a Care Navigator call you within 1 business day at janssencompass.com/signup

IMPORTANT SAFETY INFORMATION (CONT'D)

The most common side effects of AKEEGA™ include (cont'd):

- headache
- stomach area pain
- bleeding
- urinary tract infection
- cough
- trouble sleeping
- decreased weight
- irregular heartbeat (arrhythmia)
- falls
- fever

AKEEGA™ may cause fertility problems in males, which may affect the ability to father children. Talk to your healthcare provider if you have concerns about fertility.

These are not all the possible side effects of AKEEGA™.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please see the full [Prescribing Information](#) for AKEEGA™.

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Janssen Biotech, Inc.
800 Ridgeview Drive
Horsham, PA 19044

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