

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrAKEEGA™

Niraparib and abiraterone acetate tablets

Read this carefully before you start taking AKEEGA™ and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about AKEEGA™.

Serious Warnings and Precautions

- AKEEGA™ may cause **hypertension** (high blood pressure), **hypokalemia** (low blood potassium) and **peripheral edema** (swelling of the legs or hands caused by fluid retention). These will need to be treated before starting AKEEGA™. Your healthcare professional will do tests to check these problems monthly.
- Tell your healthcare professional if you have a history of heart failure, heart attack, or other heart problems. This will help avoid side effects and ensure proper use of AKEEGA™.
- If you have moderate to serious liver problems, you should not take AKEEGA™.
- Myelodysplastic Syndrome (MDS) or Acute Myeloid Leukemia (AML) is a problem with the bone marrow. You may have low red, white, or platelet cell counts. This is serious and can lead to death.

What is AKEEGA™ used for?

For the following indication AKEEGA™ has been approved with conditions (NOC/c). This means it has passed Health Canada's review and can be bought and sold in Canada, but the manufacturer has agreed to complete more studies to make sure the drug works the way it should. For more information, talk to your healthcare professional.

- AKEEGA™ is used with another medicine called prednisone or prednisolone. It is used to treat adult patients with prostate cancer that has spread to other parts of the body and no longer responds to medical or surgical treatment that lowers testosterone (known as metastatic castration resistant prostate cancer). These adults must also:
 - not currently be recommended to receive chemotherapy by their healthcare professional;
 - have mild or no symptoms; and
 - have alterations in *BRCA* genes

What is a Notice of Compliance with Conditions (NOC/c)?

A Notice of Compliance with Conditions (NOC/c) is a type of approval to sell a drug in Canada.

Health Canada only gives an NOC/c to a drug that treats, prevents, or helps identify a serious or life-threatening illness. The drug must show promising proof that it works well, is of high quality, and is reasonably safe. Also, the drug must either respond to a serious medical need in Canada, or be much safer than existing treatments.

Drug makers must agree in writing to clearly state on the label that the drug was given an NOC/c, to complete more testing to make sure the drug works the way it should, to actively monitor the drug's performance after it has been sold, and to report their findings to Health Canada.

How does AKEEGA™ work?

AKEEGA™ is a dual action medicine that contains two active substances: niraparib and abiraterone acetate.

Niraparib is a type of anti-cancer medicine called a PARP inhibitor. PARP inhibitors block an enzyme called poly [adenosine diphosphate-ribose] polymerase (PARP). PARP helps cells repair damaged DNA so blocking it means that the DNA of cancer cells cannot be repaired. This results in tumour cell death, helping to control the cancer.

Abiraterone acetate stops your body from making testosterone. This can slow the growth of prostate cancer as testosterone promotes cancer cell growth.

What are the ingredients in AKEEGA™?

Medicinal ingredients: niraparib (as niraparib tosylate), abiraterone acetate

Non-medicinal ingredients:

Colloidal anhydrous silica, crospovidone, glycerol monocaprylocaprate, hypromellose, iron oxide (E172), iron oxide red (E172), iron oxide yellow (E172), lactose monohydrate, magnesium stearate, polyvinyl alcohol, silicified microcrystalline cellulose, sodium lauryl sulfate, talc, titanium dioxide (E171)

AKEEGA™ comes in the following dosage forms:

tablets in the following strengths:

- **100 mg niraparib** (as niraparib tosylate) and **500 mg abiraterone acetate**: orange oval tablets, debossed with "N100 A" on one side and plain on the other side.
- **50 mg niraparib** (as niraparib tosylate) and **500 mg abiraterone acetate**: yellowish orange to yellowish brown oval tablets, debossed with "N 50 A" on one side and plain on the other side.

Both these strengths are available in bottles containing 60 tablets each.

Do not use AKEEGA™ if:

- you are allergic to niraparib or abiraterone acetate or any of the other ingredients of this medicine (see **What are the ingredients in AKEEGA™?**).
- you are a woman. AKEEGA™ is for use in male patients only.
- you have moderate or severe liver disease. Your healthcare professional will decide whether AKEEGA™ can be used if you have mild liver problems.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take AKEEGA™. Talk about any health conditions or problems you may have, including if you:

- have low blood-cell count on testing. AKEEGA™ lowers your blood-cell counts, such as your red blood-cell count (anemia), white blood-cell count (neutropenia), or blood-platelet count (thrombocytopenia).

- have or have had high blood pressure or other heart or blood vessel problems. For example, heart failure, irregular or rapid heart rate, shortness of breath.
- have low blood potassium. Low blood potassium may increase the risk of heart rhythm problems.
- have gained weight rapidly, or have swelling in the feet, ankles, or legs.
- have liver problems.
- have low levels of sugar in the blood.
- have an intolerance to lactose. This is because AKEEGA™ contains lactose.
- are 75 years of age or older.

Other warnings you should know about:

AKEEGA™ must be taken on an empty stomach since food can increase the blood level of AKEEGA™ and this may be harmful. Do NOT eat any solid or liquid food two hours before taking AKEEGA™ and for at least one hour after taking AKEEGA™.

High blood pressure (hypertension)

- AKEEGA™ may cause high blood pressure.
- To reduce the chance of developing high blood pressure, heart problems or low blood potassium, your healthcare professional will prescribe either prednisone or prednisolone. You need to take one of these drugs daily while you are taking AKEEGA™.
- You may also be advised by your healthcare professional to monitor your blood pressure at home. Your healthcare professional will give you instructions on when to contact them in case of a rise in blood pressure.

Posterior Reversible Encephalopathy Syndrome (PRES)

PRES is a rare neurological side effect. Cases of PRES has been reported with the niraparib component of AKEEGA™. Talk to your healthcare professional **right away** if you develop the following symptoms: headaches, vision changes, confusion, or seizure.

Low blood sugar (hypoglycemia)

- AKEEGA™ may affect your blood sugar levels if you have diabetes. Your blood sugar may drop if you take AKEEGA™ plus prednisone/prednisolone with some medicines for diabetes such as pioglitazone or repaglinide.
- Tell your healthcare professional if you take a medicine for diabetes and notice a drop in your blood sugar while monitoring your blood sugar.

Male patients

- During treatment with AKEEGA™, use a condom along with another effective birth control method each time you have sex with a woman who is pregnant, may be pregnant or could get pregnant. Continue using condom and another effective birth control method for 3 months after your last dose.
- If your sexual partner becomes pregnant or think they may be pregnant during your treatment with AKEEGA™, talk to your healthcare professional right away.
- Treatment with AKEEGA™ may affect your ability to have children. Talk to your healthcare professional if you have concerns about this.

Females

- AKEEGA™ is not for use in women.
- AKEEGA™ may harm an unborn baby.
- Women who are pregnant or may be pregnant should not handle AKEEGA™ without protective gloves.

Sensitivity to sunlight (photosensitivity)

- Photosensitivity was reported in patients treated with niraparib, a component of AKEEGA™.
- You should avoid sun exposure during treatment with AKEEGA™. When in the sunlight, wear a sunscreen with a high protection factor of at least SPF 15 and protective clothing.

Check-ups and testing

You will have regular visits with your healthcare professional, before, during and after treatment with AKEEGA™. They will:

- Do blood tests to check your blood cell count, liver enzyme levels, blood potassium levels.
- Check your blood pressure.
- Monitor for side effects of your treatment with AKEEGA™ and prednisone or prednisolone.

Driving and using machinery

AKEEGA™ may cause weakness, fatigue and dizziness. Before you drive or do tasks that require special attention, wait until you know how you respond to AKEEGA™.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements, or alternative medicines.

The following may interact with AKEEGA™:

- medicines typically used to treat epilepsy (seizures) such as phenytoin, carbamazepine, phenobarbital
- medicines to treat bacterial infections such as rifampicin, rifabutin
- an herbal treatment for depression called St. John's wort
- medicines to treat psoriasis, rheumatoid arthritis such as such as ciclosporin, tacrolimus, methotrexate
- medicines for pain such as alfentanil, ergotamine, codeine, oxycodone, and tramadol
- medicines for schizophrenia (mental disorder) such as pimozide, quetiapine, haloperidol, risperidol, or depression such as desipramine, venlafaxine,
- medicines for treating malaria such as halofantrine, clozapine,
- medicines used to treat asthma such as theophylline
- medicines used to treat parkinsons disease (progressive movement disorder) such as ropinirole,
- medicines used to treat high blood pressure such as metoprolol, propranolol, or abnormal heart rhythm such as propafenone, flecainide, or for high cholesterol such as rosuvastatin, simvastatin, atorvastatin, and methotrexate
- medicines used to treat diabetes, such as pioglitazone, repaglinide and metformin
- medicines used in cancer treatment such as irinotecan, radiotherapy

You should not start or stop any medicine before you talk with the healthcare professional that prescribed AKEEGA™.

How to take AKEEGA™:

- Take AKEEGA™ exactly as your healthcare provider tells you.
- Take your prescribed dose of AKEEGA™ once a day.
- **Take AKEEGA™ on an empty stomach.** Do NOT eat food at least two hours before taking AKEEGA™ and at least one hour after taking AKEEGA™. Taking AKEEGA™ with food causes more of this 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 the tablets.
- Do NOT stop taking your prescribed dose of AKEEGA™ without talking to your healthcare professional first.
- AKEEGA™ is taken with a medicine called prednisone or prednisolone. Take the prednisone or prednisolone exactly as your healthcare professional tells you. They will tell you how much of this medicine to take and how to take it.
- You must also start or continue a gonadotropin-releasing hormone (GnRH) analog therapy during your treatment with AKEEGA™ unless you had surgical castration. This is a surgery to remove your testicles to lower the amount of testosterone in your body.

Usual dose:

Recommended adult dose: 200 mg niraparib and 1000 mg abiraterone acetate. To make this dose, take two 100 mg / 500 mg tablets.

Your healthcare professional may change your dose, temporarily stop or completely stop treatment with AKEEGA™. This may happen if you have certain side effects while taking AKEEGA™.

Overdose:

If you think you, or a person you are caring for, have taken too much AKEEGA™, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose of AKEEGA™, prednisone or prednisolone, take your normal dose as soon as possible on the same day. Return to your normal daily dose and normal daily schedule on the following day. DO NOT take extra tablets to make up the missed dose.

What are possible side effects from using AKEEGA™?

These are not all the possible side effects you may have when taking AKEEGA™. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- Decreased appetite
- Difficulty sleeping
- Feeling dizzy
- Constipation
- Shortness of breath

- Nausea and vomiting
- Joint pain
- Feeling weak and very tired
- Increased sensitivity to the sun

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Anemia (low red blood cells): Being short of breath, feeling very tired, having pale skin, loss of energy or extreme weakness, fast heartbeat.		✓	
Hypertension (high blood pressure): shortness of breath, fatigue, dizziness or fainting, chest pain or pressure, swelling in your ankles and legs, bluish colour to your lips and skin, racing pulse or heart palpitations	✓		
Thrombocytopenia (low blood platelets): bruising or bleeding for longer than usual if you hurt yourself - these may be signs of a low blood platelet count.		✓	
Neutropenia or Leukopenia (low white blood cells): Fever or infection, chills, aches and pain and flu-like symptoms. Some infections can be serious and may lead to death.		✓	
Hypokalemia (low level of potassium in the blood): Muscle weakness, muscle twitches or a pounding heartbeat, cramping, constipation, fatigue, tingling or numbness.			✓
COMMON			
Palpitations (Fast, irregular heartbeats)		✓	
Urinary tract infection (infection in urinary system including kidneys, ureters, bladder, and urethra): Burning or pain during urination, frequent urination, blood in urine, pain in the pelvis, strong smelling urine, cloudy urine.		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Thromboembolism (blood clot in a vein or artery): pain or tenderness or swelling in your arm or leg, skin that is red or warm, coldness, tingling or numbness, pale skin, muscle pain or spasms, weakness		✓	
UNCOMMON			
Arrhythmias, including QT prolongation and Torsades de Pointes (irregular heart-beat disorders): associated with feeling faint, lightheaded, chest pain, a racing heartbeat, a slow heartbeat, shortness of breath, sweating, or a fluttering in your chest.		✓	
VERY RARE			
Hypoglycemia (low blood sugar): Thirst, frequent urination, hunger, nausea and dizziness, fast heartbeat, tingling, trembling, nervousness, sweating, low energy (low blood sugar)		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store AKEEGA™ tablets at room temperature at 15–30°C in original container.
- Keep out of reach and sight of children.
- Do not use after the expiry date which is stated on the label. The expiry date refers to the last day of the month.
Do not throw away any drugs via wastewater or household waste. Ask your pharmacist how to throw away drugs you no longer use.

If you want more information about AKEEGA™:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website : www.janssen.com/canada, or contact the manufacturer, Janssen Inc., at: 1-800-567-3331 or 1-800-387-8781.

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Janssen Inc., Toronto, Ontario M3C 1L9

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