

Package leaflet: Information for the user

Akeega 50 mg/500 mg film-coated tablets niraparib/abiraterone acetate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet (see section 4).

What is in this leaflet

1. What Akeega is and what it is used for
2. What you need to know before you take Akeega
3. How to take Akeega
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1. What Akeega is and what it is used for

Akeega is a medicine that contains two active substances: niraparib and abiraterone acetate, and works in two different ways.

Akeega is used to treat adult men with prostate cancer who have changes in certain genes and whose prostate cancer has spread to other parts of the body and no longer responds to medical or surgical treatment that lowers testosterone (also called metastatic castration-resistant prostate cancer).

Niraparib is a type of cancer medicine called a PARP inhibitor. PARP inhibitors block an enzyme called poly [adenosine diphosphate-ribose] polymerase (PARP). PARP helps cells repair damaged DNA. When PARP is blocked, cancer cells cannot repair their DNA, resulting in tumour cell death and helping to control the cancer.

Abiraterone stops your body from making testosterone; this can slow the growth of prostate cancer.

When you take this medicine, your doctor will also prescribe another medicine called prednisone or prednisolone. This is to lower your chances of getting high blood pressure, having too much water in your body (fluid retention), or having reduced levels of a chemical known as potassium in your blood.

2. What you need to know before you take Akeega

Do not take Akeega:

- if you are allergic to niraparib or abiraterone acetate or any of the other ingredients of this medicine - listed in section 6.
- if you are a woman who is or can become pregnant.
- if you have severe liver damage.
- in combination with Ra-223 treatment (which is used to treat prostate cancer). This is because of a possible increase in the risk of bone fracture or death.

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

Warnings and precautions

Talk to your doctor or pharmacist before or while taking this medicine if you have:

- low blood cell counts. Signs and symptoms you need to look out for include fatigue, fever or infection, and abnormal bruising or bleeding. Akeega may also lower your blood cell counts. Your doctor will test your blood regularly throughout your treatment.
- high blood pressure or heart failure or low blood potassium (low blood potassium may increase the risk of heart rhythm problems), have had other heart or blood vessel problems, have an irregular or rapid heart rate, shortness of breath, gained weight rapidly, or swelling in the feet, ankles, or legs. Your doctor will measure your blood pressure regularly throughout your treatment.
- headaches, vision changes, confusion, or seizure. These may be signs of a rare neurological side effect named posterior reversible encephalopathy syndrome (PRES) that has been associated with use of niraparib, an active ingredient of Akeega.
- high fever, fatigue and other signs and symptoms of severe infection.
- blood clots in the lungs or legs, or have had them in the past.
- liver problems.
- low or high levels of sugar in the blood.
- muscle weakness and/or muscle pain.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking this medicine.

If you develop abnormal blood-cell counts for a long period of time while taking Akeega, this may be a sign of more serious problems with the bone marrow such as ‘myelodysplastic syndrome’ (MDS) or ‘acute myeloid leukaemia’ (AML). Your doctor may want to test your bone marrow to check for these problems.

Before taking Akeega, also talk to your doctor or pharmacist about:

- the effect Akeega may have on your bones.
- taking prednisone or prednisolone (another medicine you must take with Akeega)

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking this medicine.

Blood monitoring

Akeega may affect your liver, but you may not notice any symptoms of liver problems. When you are taking this medicine, your doctor will therefore check your blood periodically to look for any effects on your liver.

Children and adolescents

This medicine is not for use in children and adolescents. If Akeega is accidentally swallowed by a child or adolescent, take them to the hospital immediately and take this package leaflet with you to show to the emergency doctor.

Other medicines and Akeega

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. This is because Akeega can affect the way some other medicines work. Also, some other medicines can affect the way Akeega works.

Treatment with medicines that stop the body from producing testosterone, may increase the risk of heart rhythm problems. Tell your doctor if you are receiving medicine:

- to treat heart rhythm problems (e.g. quinidine, procainamide, amiodarone and sotalol);

- known to increase the risk of heart rhythm problems (e.g., methadone), used for pain relief and part of drug addiction detoxification; moxifloxacin, an antibiotic; antipsychotics, used for serious mental illnesses.

Tell your doctor if you are taking any of the medicines listed above.

Akeega with food

- This medicine must not be taken with food (see section 3, “Taking Akeega”), as this may increase your risk of side effects.

Pregnancy and breast-feeding

Akeega is not for use in women.

- This medicine may cause harm to the unborn child if it is taken by women who are pregnant.
- Women who are pregnant or who may become pregnant should wear gloves if they need to touch or handle Akeega.

Contraception for men using Akeega

- If you are having sex with a woman who can become pregnant, use a condom and another effective birth control method. Use contraception during treatment and for 4 months after stopping. Talk to your doctor if you have any questions about contraception.
- If you are having sex with a pregnant woman, use a condom to protect the unborn child.

Driving and using machines

Taking Akeega may make you feel weak, unfocused, tired or dizzy. This may influence your ability to drive and use machines. Use caution when driving or using machines.

Akeega contains lactose and sodium

- Akeega contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
- This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially ‘sodium-free’.

3. How to take Akeega

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

How much to take

The recommended starting dose is 200 mg/1 000 mg once a day.

Taking Akeega

- Take this medicine by mouth.
- **Do not take Akeega with food.**
- Take Akeega tablets as a single dose once daily on an empty stomach **at least one hour before or at least two hours after eating** (see section 2, “Akeega with food”).
- Swallow the tablets whole with water. Do not break, crush, or chew the tablets. This will ensure the medicine works as well as possible.
- Akeega is taken with a medicine called prednisone or prednisolone.
 - Take the prednisone or prednisolone exactly as your doctor has told you.
 - You need to take prednisone or prednisolone every day while you are taking Akeega.
 - The amount of prednisone or prednisolone you take may need to be changed if you have a medical emergency. Your doctor will tell you if you need to change the amount of prednisone or prednisolone you take. Do not stop taking prednisone or prednisolone unless your doctor tells you to.

Your doctor may also prescribe other medicines while you are taking Akeega.

If you take more Akeega than you should

If you take more tablets than you should contact your doctor. You may have an increased risk of side effects.

If you forget to take Akeega

If you forget to take Akeega or prednisone or prednisolone, take your usual dose as soon as you remember on the same day.

If you forget to take Akeega or prednisone or prednisolone for more than one day - talk to your doctor straight away.

Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

If you stop taking Akeega

Do not stop taking Akeega or prednisone or prednisolone unless your doctor tells you to.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects

Stop taking Akeega and seek medical attention immediately if you notice any of the following symptoms:

Very common (may affect more than 1 in 10 people)

- Bruising or bleeding for longer than usual if you hurt yourself - these may be signs of a low blood platelet count (thrombocytopenia).
- Being short of breath, feeling very tired, having pale skin, or fast heartbeat - these may be signs of a low red blood cell count (anaemia).
- Fever or infection – low white blood cell count (neutropenia) can increase your risk for infection. Signs may include fever, chills, feeling weak or confused, cough, pain or burning feeling when passing urine. Some infections can be serious and may lead to death.
- Muscle weakness, muscle twitching or a pounding heart beat (palpitations). These may be signs that the level of potassium in your blood is low (hypokalaemia).
- Increased level of the enzyme ‘alkaline phosphatase’ in the blood

Not known (cannot be estimated) – not reported with the use of Akeega but reported with use of niraparib or abiraterone acetate (components of Akeega)

- Allergic reaction (including severe allergic reaction that can be life-threatening). Signs include: raised and itchy rash (hives) and swelling-sometimes of the face or mouth (angioedema), causing difficulty in breathing, and collapse or loss of consciousness.
- A sudden increase in blood pressure, which may be a medical emergency that could lead to organ damage or can be life-threatening.

Other side effects

Talk to your doctor if you get any other side effects. These can include:

Very common (may affect more than 1 in 10 people):

- urinary tract infection
- low number of white blood cells (leukopenia), seen in blood tests

- low number of a type of white blood cell (lymphopenia), seen in blood tests
- high blood pressure
- decreased appetite
- difficulty sleeping (insomnia)
- feeling dizzy
- shortness of breath
- stomach pain
- constipation
- feeling sick (nausea)
- vomiting
- back pain
- joint pain
- feeling very tired
- feeling weak
- high level of sugar in blood
- weight loss
- swollen hands, ankles, or feet
- increased level of 'creatinine' in the blood

Common (may affect up to 1 in 10 people):

- pneumoniae
- lung infection (bronchitis)
- infection of the nose and throat (nasopharyngitis)
- high level of a type of fat (hypertriglyceridaemia) in the blood
- depression
- feeling anxious
- headache
- fast heart beat
- fast or uneven heart beat (palpitations)
- irregular heart beat (atrial fibrillation)
- heart failure, causing shortness of breath and swollen legs
- heart attack
- chest discomfort, often brought on by physical activity
- cough
- blood clot in the lungs, causing chest pain and shortness of breath
- inflamed lungs
- indigestion
- diarrhoea
- bloating
- sores in the mouth
- dry mouth
- liver failure
- skin rash
- muscle aches
- blood in the urine
- increased level of the enzyme 'aspartate aminotransferase' in the blood
- increased level of the enzyme 'alanine aminotransferase' in the blood
- bone fractures

Uncommon (may affect up to 1 in 100 people):

- severe infection (sepsis) that spreads from the urinary tract throughout the body
- inflamed eye (conjunctivitis)
- feeling confused
- change in sense of taste

- abnormal ECG (electrocardiogram), which could be a sign of heart problems
- nose bleeds
- inflammation of the protective linings in the body cavities, such as the nose, mouth, or digestive system
- increased sensitivity of the skin to sunlight
- increased level of 'gamma-glutamyltransferase' in the blood

Not known (cannot be estimated) – not reported with the use of Akeega but reported with use of niraparib or abiraterone acetate (components of Akeega)

- low numbers of all types of blood cells (pancytopenia)
- brain condition with symptoms including seizures (fits), headache, confusion, and changes in vision (posterior reversible encephalopathy syndrome or PRES), which is a medical emergency that could lead to organ damage or can be life-threatening
- adrenal gland problems (related to salt and water problems) where too little hormone is produced which may cause problems like weakness, tiredness, loss of appetite, nausea, dehydration and skin changes
- difficulty thinking, remembering information, or solving problems (cognitive impairment)
- inflamed lungs caused by an allergic reaction (allergic alveolitis)
- allergic reaction
- muscle disease (myopathy), which may cause muscle weakness, stiffness or spasms
- breakdown of muscle tissue (rhabdomyolysis), which may cause muscle cramps or pains, tiredness and dark urine

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Akeega

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the container (blister foil, inner wallet, outer wallet, and carton) after EXP. The expiry date refers to the last day of that month.

Store below 30°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Akeega contains

- The active substances are niraparib and abiraterone acetate. Each film-coated tablet contains 50 mg niraparib and 500 mg abiraterone acetate.
- The other ingredients of the tablet core are colloidal anhydrous silica, crospovidone, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium lauryl sulfate. The film-coating contains iron oxide black (E172), iron oxide red (E172), iron oxide yellow (E172), sodium lauryl sulphate, glycerol monocaprylocaprate, polyvinyl alcohol, talc, and titanium dioxide (E171) (see section 2, Akeega contains lactose and sodium).

What Akeega looks like and contents of the pack

Akeega film-coated tablets are yellowish orange to yellowish brown oval tablet, debossed with “N 50 A” on one side and plain on the other side.

Each 28-day carton contains 56 film-coated tablets in two cardboard wallet packs of 28 film-coated tablets each.

Not all pack sizes and concentrations may be marketed.

Marketing Authorisation Holder

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Manufacturer

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To contact us, please visit our website www.janssen.com/contact-us

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THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament. The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of the reach of children

Council of Arab Health Ministers, Union of Arab Pharmacists