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Akeega (*niraparib / abiraterone acetate*)

An overview of Akeega and why it is authorised in the EU

What is Akeega and what is it used for?

Akeega is a cancer medicine for treating adult patients with castration-resistant prostate cancer that has spread to other parts of the body.

It is used when medical or surgical treatment to lower testosterone levels (castration) has not worked.

Akeega is for patients who have genetic mutations known as BRCA 1/2 mutations and who cannot have chemotherapy. It is used in combination with prednisolone or another medicine prednisone, which is converted into prednisolone.

Akeega contains two active substances: niraparib and abiraterone acetate.

How is Akeega used?

Akeega is available as tablets to be taken by mouth on an empty stomach. The patient should take the medicine once a day for as long as they benefit from it or do not have unacceptable side effects.

The medicine can only be obtained with a prescription. For more information about using Akeega, see the package leaflet or contact your doctor or pharmacist.

How does Akeega work?

Akeega contains two active substances: niraparib and abiraterone acetate. Niraparib blocks the action of enzymes called PARP-1 and PARP-2, which help to repair damaged DNA in cells when the cells divide to make new cells. The blocking of the PARP enzymes prevents cancer cells from repairing damaged DNA, and, as a result, the cancer cells die.

The other active substance, abiraterone acetate, stops the body producing testosterone by blocking an enzyme called CYP17 found in the testes and elsewhere in the body. Because the cancer needs a supply of testosterone to survive and grow, abiraterone acetate helps slow the growth of the prostate cancer.

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What benefits of Akeega have been shown in studies?

A main study involving 225 patients with castration-resistant prostate cancer and BRCA 1/2 mutations showed that Akeega was effective at slowing the worsening of the disease.

In this study, the time it took for scans to show the disease getting worse was around 17 months in patients who received Akeega, compared to 11 months in those treated with abiraterone acetate plus placebo (a dummy treatment). Patients in both groups also received prednisone.

What are the risks associated with Akeega?

For the full list of side effects and restrictions with Akeega, see the package leaflet.

The most common side effects with Akeega (which may affect more than 1 in 10 people) include anaemia (low levels of red blood cells), high blood pressure, constipation, tiredness, nausea, thrombocytopenia (low levels of blood platelets), difficulty breathing, back pain, reduced appetite, neutropenia (low levels of neutrophils, a type of white blood cell), joint pain, vomiting, low levels of potassium, dizziness, difficulty sleeping, high blood glucose levels and urinary tract infection.

The most serious side effects include anaemia, high blood pressure, thrombocytopenia, neutropenia and increase levels of the liver enzyme alkaline phosphatase.

Akeega must not be used in patients with severe liver problems and should not be administered in combination with Radium-223, a type of radiotherapy.

Akeega is not for use in women. As it may cause harm to the unborn baby, patients engaged in sexual activity with a woman who is pregnant or can become pregnant should use contraception.

Why is Akeega authorised in the EU?

The main study showed that Akeega was effective at slowing the worsening of castration-resistant prostate cancer that has spread to other parts of the body in patients with BRCA 1/2 mutations who cannot receive chemotherapy.

Most of side effects of Akeega are those seen when the individual active substances are used alone. Although some side effects were serious, they were generally manageable. The European Medicines Agency therefore decided that the benefits of Akeega are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Akeega?

The company that markets Akeega will provide further data on how well treatment prolongs patients' lives.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Akeega have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Akeega are continuously monitored. Suspected side effects reported with Akeega are carefully evaluated and any necessary action taken to protect patients.

Other information about Akeega

Akeega received a marketing authorisation valid throughout the EU on 19 April 2023.

Further information on Akeega can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/akeega.

This overview was last updated in 04-2023.