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Abiraterone Accord (*abiraterone acetate*)

An overview of Abiraterone Accord and why it is authorised in the EU

What is Abiraterone Accord and what is it used for?

Abiraterone Accord is a cancer medicine used to treat men with metastatic prostate cancer. This is cancer that affects the prostate gland (a gland of the male reproductive system). It is used when the cancer has spread to other parts of the body (metastatic).

Abiraterone Accord is used together with prednisone or prednisolone (anti-inflammatory medicines):

- when the cancer is newly diagnosed, high risk and sensitive to hormones; Abiraterone Accord is then used in combination with a treatment called androgen deprivation therapy;
- when medical castration (using medicines to stop the production of male hormones) with an androgen deprivation therapy has not worked or no longer works in men who have either no symptoms or only mild symptoms of the disease, and who do not yet need chemotherapy (cancer medicines);
- when medical or surgical castration and chemotherapy containing docetaxel have not worked or no longer work.

Abiraterone Accord contains the active substance abiraterone acetate and is a 'generic medicine'. This means that Abiraterone Accord contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU called Zytiga. For more information on generic medicines, see the question-and-answer document here.

How is Abiraterone Accord used?

Abiraterone Accord is available as tablets and can only be obtained with a prescription. The recommended dose is 1,000 mg taken once a day on an empty stomach. This means that the patient should wait at least 2 hours after eating before taking the medicine and he must not eat for at least 1 hour after taking the medicine. If patients develop liver problems, treatment should be stopped. Treatment may be resumed at a reduced dose if liver function returns to normal.

For more information about using Abiraterone Accord, see the package leaflet or contact your doctor or pharmacist.

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How does Abiraterone Accord work?

The active substance in Abiraterone Accord, abiraterone acetate, is changed in the body to abiraterone which stops the body producing testosterone, a male hormone. Abiraterone does this 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, by reducing the production of testosterone, Abiraterone Accord may slow the growth of the prostate cancer.

How has Abiraterone Accord been studied?

Studies on the benefits and risks of the active substance in the authorised uses have already been carried out with the reference medicine, Zytiga, and do not need to be repeated for Abiraterone Accord.

As for every medicine, the company provided studies on the quality of Abiraterone Accord. The company also carried out studies that showed that it is 'bioequivalent' to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

What are the benefits and risks of Abiraterone Accord?

Because Abiraterone Accord is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Abiraterone Accord authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Abiraterone Accord has been shown to have comparable quality and to be bioequivalent to Zytiga. Therefore, the Agency's view was that, as for Zytiga, the benefits of Abiraterone Accord outweigh the identified risks and it can be authorised for use in the EU.

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

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

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

Other information about Abiraterone Accord

Abiraterone Accord received a marketing authorisation valid throughout the EU on 26 April 2021.

Further information on Abiraterone Accord can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/abiraterone-accord. Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 04-2021.