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Abiraterone Mylan (*abiraterone acetate*)

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

What is Abiraterone Mylan and what is it used for?

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

- when the cancer is newly diagnosed, high risk and sensitive to hormones; Abiraterone Mylan 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 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 Mylan contains the active substance abiraterone acetate and is a 'generic medicine'. This means that Abiraterone Mylan 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 Mylan used?

Abiraterone Mylan 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 two hours after eating before taking the medicine and must not eat for at least one hour after taking the medicine. If the patient develops liver problems, treatment should be stopped. Treatment may be resumed at a reduced dose if the liver function returns to normal.

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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

How does Abiraterone Mylan work?

The active substance in Abiraterone Mylan, 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 Mylan can slow the growth of the prostate cancer.

How has Abiraterone Mylan 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 Mylan.

As for every medicine, the company provided data on the quality of Abiraterone Mylan. 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 Mylan?

Because Abiraterone Mylan 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 Mylan authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Abiraterone Mylan 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 Mylan 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 Mylan?

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

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

Other information about Abiraterone Mylan

Abiraterone Mylan received a marketing authorisation valid throughout the EU on 20 August 2021.

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

This overview was last updated in 08-2021.