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EPAR summary for the public

Zytiga

abiraterone acetate

This is a summary of the European public assessment report (EPAR) for Zytiga. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Zytiga.

For practical information about using Zytiga, patients should read the package leaflet or contact their doctor or pharmacist.

What is Zytiga and what is it used for?

Zytiga is a medicine used to treat cancer of the prostate (a gland of the male reproductive system) in adult men when the cancer is metastatic (has spread to other parts of the body).

Zytiga is used together with the medicines prednisone or prednisolone in the following situations:

- when the cancer is newly diagnosed, high risk and still sensitive to hormones; Zytiga 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.

Zytiga contains the active substance abiraterone acetate.

How is Zytiga used?

Zytiga is available as tablets (250 and 500 mg) and can only be obtained with a prescription.

The recommended dose of Zytiga is 1,000 mg taken once a day at least two hours after eating and at least one hour before further food. If patients develop liver problems treatment should be stopped. Treatment may be resumed at a reduced dose if liver function returns to normal.

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For further information, see the package leaflet.

How does Zytiga work?

The active substance in Zytiga, 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, Zytiga may slow the growth of the prostate cancer.

What benefits of Zytiga have been shown in studies?

Zytiga was compared with placebo (a dummy treatment) in three main studies. In the studies, patients were also treated with prednisone or prednisolone.

One study involved 1,209 patients with newly diagnosed, high-risk, hormone-sensitive, metastatic prostate cancer. The main measure of effectiveness was how long patients lived without their disease getting worse. Patients treated with Zytiga lived for an average of 33 months without their disease getting worse, compared with around 15 months for patients given placebo.

The second study involved 1,088 men with metastatic prostate cancer who had either no symptoms or only mild symptoms of the disease and for whom castration treatment had not worked or had stopped working. Patients treated with Zytiga lived for an average of around 16 months without their disease getting worse, compared with around 8 months in patients given placebo.

In a third study involving 1,195 men with metastatic prostate cancer whose disease had got worse despite surgical or medical castration treatment and chemotherapy with docetaxel, the main measure of effectiveness was overall survival (how long the patients lived). Patients treated with Zytiga lived for just under 15 months from the start of treatment compared with just under 11 months for patients given placebo.

What are the risks associated with Zytiga?

The most common side effects with Zytiga (seen in more than 1 patient in 10) are urinary tract infection, hypokalaemia (low blood potassium levels), high blood pressure, peripheral oedema (swelling of the limbs due to fluid retention) and increases in liver enzymes. Other important side effects include heart problems, liver problems, fractures and allergic alveolitis (a lung reaction causing cough and shortness of breath). For the full list of all side effects reported with Zytiga, see the package leaflet.

Zytiga must not be used in patients with severely reduced liver function. It is not for use in women and must not be given to women who are or who may be pregnant. For the full list of restrictions, see the package leaflet.

Why is Zytiga approved?

The European Medicines Agency decided that Zytiga’s benefits are greater than its risks and recommended that it be approved for use in the EU. The Agency noted that Zytiga in combination with prednisone or prednisolone has been shown to either delay progression of the disease or improve survival compared with placebo. Zytiga is well tolerated and its risks are considered manageable.

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

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

Other information about Zytiga

The European Commission granted a marketing authorisation valid throughout the European Union for Zytiga on 5 September 2011.

The full EPAR for Zytiga can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Zytiga, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 11-2017.

MA (EU) number	(Invented) name	Strength	Pharmaceutical Form	Route of Administration	Immediate Packaging	Pack size
EU/1/11/714/001	Zytiga	250 mg	Tablet	Oral use	bottle	120 tablets
EU/1/11/714/002	Zytiga	500 mg	Film-coated tablet	Oral use	PVdC/PE/PVC/alu blister	56 tablets
EU/1/11/714/003	Zytiga	500 mg	Film-coated tablet	Oral use	PVdC/PE/PVC/alu blister	60 tablets