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Daurismo (*glasdegib*)

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

What is Daurismo and what is it used for?

Daurismo is a cancer medicine for treating adults with newly-diagnosed acute myeloid leukaemia (AML), a cancer of white blood cells.

It is used in combination with a low dose of cytarabine (another cancer medicine) when the patient cannot be treated with standard chemotherapy.

The active substance in Daurismo is glasdegib.

Acute myeloid leukaemia is rare, and Daurismo was designated an 'orphan medicine' (a medicine used in rare diseases) on 16 October 2017. Further information on the orphan designation can be found here: ema.europa.eu/medicines/human/orphan-designations/eu3171923.

How is Daurismo used?

Daurismo can only be obtained with a prescription and treatment should be prescribed and supervised by a doctor experienced in using cancer medicines.

Daurismo is available as tablets and the recommended starting dose is 100 mg once daily taken by mouth. The medicine is given together with a low dose of cytarabine, which is given by injection under the skin. Treatment can continue for as long as the patient benefits from it. If certain side effects occur, the doctor may reduce the dose of Daurismo or stop the treatment temporarily or permanently. Treatment with Daurismo together with other medicines that speed up the breakdown of Daurismo in the body called 'moderate CYP3A4 inducers' should be avoided, or if it cannot be avoided, the dose of Daurismo should be increased.

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

How does Daurismo work?

The active substance in Daurismo, glasdegib, blocks a protein called 'SMO'. When SMO is not working normally, it can play a role in growth of cancer cells and prevent cancer medicines from working. Blocking SMO reduces the ability of cancer cells to survive and grow while helping to make cancer treatment more effective.

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What benefits of Daurismo have been shown in studies?

In a main study with 116 patients with newly-diagnosed AML who were not able to have standard chemotherapy, Daurismo with cytarabine prolonged patients' lives compared with patients receiving cytarabine alone. Patients receiving Daurismo and low dose of cytarabine lived on average 8.3 months compared with 4.3 months for those receiving low-dose cytarabine alone.

What are the risks associated with Daurismo?

The most common side effects with Daurismo (which may affect more than 2 in 10 people) are anaemia (low red blood cell counts), bleeding, febrile neutropenia (low white blood cell counts with fever), nausea (feeling sick), decreased appetite, tiredness, muscle spasms, thrombocytopenia (low blood platelet counts), fever, diarrhoea, pneumonia (lung infection), dysgeusia (taste disturbances), peripheral oedema (swelling especially of the ankles and feet), constipation, abdominal (belly) pain, rash, dyspnoea (difficulty breathing), vomiting and decrease in weight.

Daurismo can harm the unborn child, causing severe and life-threatening birth defects or death in the womb or shortly after birth. Daurismo must therefore never be used by women who are pregnant. Women who are able to become pregnant should always use effective contraception during treatment and for at least 30 days after the last dose.

Daurismo may be present in semen. Male patients should always use effective contraception with their female partners, including a condom (with spermicide, if available), during treatment and for at least 30 days after the last dose.

Daurismo could impair fertility in men. Men may wish to consult their doctor about fertility preservation before starting treatment.

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

Why is Daurismo authorised in the EU?

Daurismo has been shown to prolong patients' lives when added to a low dose of cytarabine in patients with acute myeloid leukaemia who have a poor prognosis and few alternatives as they are not able to have standard chemotherapy as a first treatment. Side effects are considered manageable. The European Medicines Agency therefore decided that Daurismo's benefits 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 Daurismo?

The company that markets Daurismo will provide an alert card to be given to male patients informing them about the medicine passing into semen, measures to avoid risks of harm to the unborn child and the potential effects on fertility.

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

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

Other information about Daurismo

Daurismo received a marketing authorisation valid throughout the EU on 26 June 2020.

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

This overview was last updated in 06-2020.