

Package leaflet: Information for the patient

Daurismo 25 mg film-coated tablets **Daurismo 100 mg film-coated tablets** glasdegib

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Daurismo is and what it is used for
2. What you need to know before you take Daurismo
3. How to take Daurismo
4. Possible side effects
5. How to store Daurismo
6. Contents of the pack and other information

1. What Daurismo is and what it is used for

Daurismo is a cancer medicine containing the active substance glasdegib.

Daurismo is used with another cancer medicine, cytarabine, to treat adults newly diagnosed with a blood cancer called acute myeloid leukaemia (AML).

How Daurismo works

In AML, cancer cells called stem cells constantly make new leukaemic cancer cells. Daurismo works by blocking a key process in these stem cells, called the Hedgehog (Hh) pathway. This reduces their ability to make new cancer cells. By blocking the Hh pathway, Daurismo can also make cancer cells more sensitive to a cancer medicine, cytarabine, used to treat AML. Combining Daurismo with the medicine cytarabine may increase how long patients are likely to live by decreasing growth of the cancer and possibly by increasing cancer cell death.

If you have any questions about how Daurismo works or why this medicine has been prescribed for you, ask your doctor.

2. What you need to know before you take Daurismo

Do not take Daurismo

- if you are allergic to glasdegib or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Daurismo

- if you or your partner are able to become pregnant (see section Pregnancy, breast-feeding and fertility).
- if you have ever had QT interval prolongation (a change in electrical activity of the heart that can cause serious irregular heart rhythms) or know you are at danger of the condition.
- if you take other medicines that you have been told can prolong QT interval.
- if blood tests show you have abnormal levels of electrolytes (e.g. calcium, magnesium, potassium).
- if you have kidney problems.
- if you have a history of muscle cramps or weakness.

Tell your doctor immediately while taking this medicine

- if your muscles hurt or you have unexplained muscle cramps or weakness during treatment with Daurismo. Your doctor may need to change your dose, or stop your treatment temporarily or permanently.

Children and adolescents

Daurismo is not to be used in patients less than 18 years of age.

Other medicines and Daurismo

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription and herbal medicines. This is because Daurismo can affect the way some other medicines work. Some other medicines can affect the way Daurismo works.

In particular, the following may increase the risk of side effects with Daurismo:

- boceprevir – a medicine used to treat hepatitis C.
- cobicistat, ritonavir, telaprevir – medicines used to treat HIV infection.
- itraconazole, ketoconazole, voriconazole, posaconazole – medicines used to treat fungal infections.
- troleandomycin – a medicine used to treat bacterial infections.
- conivaptan – a medicine used to regulate imbalance of water and salt.
- amiodarone, disopyramide, dofetilide, ibutilide, sotalol, quinidine – medicines used to treat heart problems.
- droperidol, haloperidol, pimozide – medicines used to treat psychotic diseases.
- moxifloxacin – a medicine used to treat a certain type of bacterial infections.
- methadone – a medicine used to treat pain and for the treatment of opioid addiction.

The following medicines may reduce the effectiveness of Daurismo:

- carbamazepine, phenytoin, anti-epileptics – medicines used to treat seizures or fits.
- rifampicin – a medicine used to treat tuberculosis (TB).
- St. John's wort (*Hypericum perforatum*) – a herbal product used to treat mild depression and anxiety.
- enzalutamide – a medicine used to treat prostate cancer.
- mitotane – a medicine used to treat adrenal gland cancer.
- bosentan – a medicine used to treat high blood pressure.
- efavirenz, etravirine – medicines used to treat HIV infection.
- modafinil – a medicine used to treat sleep disorders.
- nafcillin – a medicine used to treat certain types of bacterial infections.

Daurismo with food and drink

Do not drink grapefruit juice or eat grapefruit while on treatment with Daurismo as it may change the amount of Daurismo in your body.

Pregnancy, breast-feeding and fertility

Pregnancy

You must not become pregnant while taking Daurismo and you must not take it if you are pregnant. Daurismo can cause severe birth defects in babies or lead to the death of an unborn baby.

Your doctor will give you more information about the effects of Daurismo on the unborn baby and will carry out a pregnancy test before you start taking the medicine.

You must talk to your doctor immediately if you or your partner become pregnant or suspect you could be pregnant during treatment and for 30 days after your last dose of Daurismo. If you are pregnant, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Contraception in women and men

Women

You should always use effective birth control (contraception) while taking Daurismo and for at least 30 days after the last dose of Daurismo. Talk to your doctor about birth control methods that are right for you and your partner.

Men

Men should always use effective contraception, including condoms (with spermicide, if available), even if you have had a vasectomy, while taking Daurismo and for at least 30 days after the last dose of Daurismo.

You should not donate semen at any time while you are taking Daurismo and for at least 30 days after your last dose.

Breast-feeding

Do not breast-feed while taking Daurismo or during the one week after the last dose of Daurismo. It is not known if Daurismo passes into your breast milk and harms your baby.

Fertility

Daurismo may affect male and female fertility. Talk to your doctor about fertility preservation before taking Daurismo.

Driving and using machines

If you feel tired, or get muscle cramps, pain or nausea (feeling sick) while on treatment with Daurismo, take special care when driving and using machines.

Daurismo contains sodium

This medicine contains less than 1 mmol sodium (less than 23 mg) per tablet, that is to say Daurismo is essentially 'sodium-free'.

Daurismo contains lactose

This medicine contains lactose (found in milk or dairy products).

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Daurismo

Take Daurismo once a day at about the same time every day. Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one tablet of 100 mg taken by mouth once a day with or without food.

If you get certain side effects while you are taking Daurismo (see section 4 “Possible side effects”), your doctor may lower your dose or stop treatment, either temporarily or permanently.

If you vomit after taking Daurismo

If you vomit after taking a dose of Daurismo, do not take an extra dose, just take your next dose at the usual time.

If you take more Daurismo than you should

If you accidentally take too many tablets, tell your doctor, pharmacist or nurse right away. You may require urgent medical attention.

If you forget to take Daurismo

If you forget to take a tablet, then take it as soon as you remember unless more than 10 hours have passed since the scheduled dose time, in which case, you should skip the dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Daurismo

Do not stop taking Daurismo unless your doctor tells you to.

It is important to take Daurismo every day, as long as your doctor prescribes it to you. If you cannot take the medicine as your doctor has prescribed, or you feel you do not need it anymore, speak with your doctor right away.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Daurismo may cause severe birth defects. It may also lead to the death of a baby before it is born or shortly after being born. You must not become pregnant while taking this medicine (see section 2, “What you need to know before you take Daurismo”).

Other side effects with Daurismo, in combination with cytarabine, include:

Very common: may affect more than 1 in 10 people

- low haemoglobin
- bleeding
- fever
- nausea
- loss of appetite
- muscle pain
- feeling tired
- decrease in the number of platelets in the blood
- diarrhoea
- pneumonia
- changes in taste
- swelling of arms and legs
- constipation
- abdominal (belly) pain
- rash
- shortness of breath
- vomiting

- weight loss
- decrease in the number of white blood cells
- decrease in the number of a type of white blood cells (neutrophils)
- joint pain
- hair loss

Common: may affect up to 1 in 10 people

- changes in the electrical activity of the heart
- heart palpitations
- blood infection
- burning sensation during urination and frequent and urgent need to urinate (may be symptoms of urinary tract infection)
- mouth irritation

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Daurismo

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the blister foil or bottle after “EXP”. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not use this medicine if the pack is damaged or shows signs of tampering.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Daurismo contains

- The active substance is glasdegib.
Daurismo 25 mg film-coated tablets: each film-coated tablet contains glasdegib maleate equivalent to 25 mg of glasdegib.
Daurismo 100 mg film-coated tablets: each film-coated tablet contains glasdegib maleate equivalent to 100 mg glasdegib.
- The other ingredients are:
Tablet core: sodium starch glycolate, microcrystalline cellulose, calcium hydrogen phosphate anhydrous, and magnesium stearate. See section 2 “Daurismo contains sodium.”
Film-coating: lactose monohydrate, hypromellose, titanium dioxide, macrogol, triacetin, iron oxide yellow, and iron oxide red (100 mg tablets only). See section 2 “Daurismo contains lactose.”

What Daurismo looks like and contents of the pack

Daurismo 25 mg film-coated tablets

- Round, yellow film-coated tablets, debossed with “Pfizer” on one side and “GLS 25” on the other side.
- Provided in blisters of 10 tablets. Each pack contains 60 tablets in either 6 blisters or in one plastic bottle.

Daurismo 100 mg film-coated tablets

- Round, pale orange film-coated tablets, debossed with “Pfizer” on one side and “GLS 100” on the other side.
- Provided in blisters of 10 tablets. Each pack contains 30 tablets in either 3 blisters or in one plastic bottle.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Pfizer Europe MA EEIG
Boulevard de la Plaine 17
1050 Bruxelles
Belgium

Manufacturer

Pfizer Manufacturing Deutschland GmbH
Betriebsstätte Freiburg
Mooswaldallee 1
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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: <http://www.ema.europa.eu>. There are also links to other websites about rare diseases and treatments.

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