Package leaflet: Information for the patient

▼ 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 Voranigo is and what it is used for

What Voranigo is and how it works
Voranigo is a cancer medicine that contains the active substance vorasidenib.

It is used as treatment for cancers of the brain called astrocytoma or oligodendroglioma in adults and adolescents from 12 years of age and older, who have had surgery as their only treatment and who do not need other treatments such as radiotherapy or chemotherapy immediately.

This medicine is only used when the cancer cells have changes in the genes (mutations) that make proteins known as IDH1 and IDH2. The doctor will have a test performed to check if the cells have this mutation before treatment starts. The IDH1 and IDH2 proteins play an important role in making energy for cells and when the *IDH1* gene or *IDH2* gene is mutated, these proteins are changed and do not function properly. This results in changes in the cells that can lead to the development of cancer.

The active substance in Voranigo, vorasidenib, blocks the abnormal IDH1 and IDH2 proteins. In patients with astrocytoma or oligodendroglioma brain cancers, these proteins are not working properly, causing the overproduction of a substance called 2-hydroxyglutarate (2-HG) that plays a part in the process of normal cells turning into cancer cells. By blocking these proteins, vorasidenib stops the abnormal production of 2-HG which helps to slow or stop the cancer from growing.

2. What you need to know before you take Voranigo

Do not take Voranigo
- if you are allergic to vorasidenib 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 Voranigo:
- if you have kidney problems
- if you have liver problems

Monitoring of liver function
Voranigo may affect how well your liver functions. Your doctor will carry out blood tests to check how well your liver is working before you are treated with Voranigo, and as necessary during the treatment. If necessary, your doctor may lower your dose or temporarily or permanently stop your treatment. Tell your doctor, pharmacist or nurse right away if you develop any of the following, which may be signs and symptoms of liver problems:
- yellowing of your skin or the white part of your eyes (jaundice)
- dark “tea-coloured” urine
- loss of appetite
- pain on the upper right side of your stomach area
- feeling weak or very tired

Pregnancy and birth control
This medicine may cause harm to the baby during pregnancy. Women who are able to become pregnant should use effective birth control during treatment and for at least 3 months after treatment has stopped.

Men who are using Voranigo should also use effective birth control during treatment and for at least 3 months after treatment has stopped if they have a partner who is able to become pregnant (see “Contraception in women and men”).

Children
Do not give this medicine to children under 12 years old. It has not been studied in this age group.

Other medicines and Voranigo
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Voranigo can affect the way some other medicines work and some other medicines can affect the way Voranigo works.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines listed below.

The following medicines may increase the risk of side effects with Voranigo by increasing the amount of Voranigo in the blood:
- **Ciprofloxacin** (used to treat bacterial infections)
- **Fluvoxamine** (used to treat depression)

The following medicines may decrease the effectiveness of Voranigo by decreasing the amount of Voranigo in the blood:
- **Rifampicin** (used to treat tuberculosis or certain other infections)
- **Phenytoin** (used to treat epilepsy)

Voranigo may decrease the effectiveness of the following medicines by decreasing the amount of these medicines in the blood:
- **Alfentanil** (used for anaesthesia in surgery)
- **Carbamazepine, fosphenytoin, phenobarbital, phenytoin** (used to treat seizures)
- **Ciclosporin, everolimus, sirolimus, tacrolimus** (medicines used after organ transplants to help control your body’s immune response)
- **Fentanyl** (used for severe pain)
- **Pimozide** (used to treat abnormal thoughts and feelings)
- **Quinidine** (used to treat abnormal heartbeat)
- **Ibrutinib, ifosfamide, tamoxifen** (used to treat certain cancers)
- **Buspirone** (used to treat nervous system disorders and/or relieve anxiety)
- **Darunavir, saquinavir, tipranavir** (medicines used to treat HIV infection)
- **Midazolam, triazolam** (used to help you sleep and/or relieve anxiety)
- **Amitriptyline, dosulepin, imipramine, trimipramine** (used to treat depression)
- **Bupropion** (used to help you stop smoking)
- **Celecoxib** (used to treat arthritis)
- **Repaglinide** (used to treat diabetes)
- **Valproic acid** (used to treat epilepsy)
- **Warfarin** (used to treat blood clots)
- **Hormonal contraceptive medicines** (medicines used to prevent pregnancy, such as birth control pills). See “Contraception in women and men” section below.

The medicines listed here may not be the only ones that could interact with Voranigo. Ask your doctor or pharmacist for advice before taking any medicine.

Pregnancy
Voranigo should not be used during pregnancy as it could harm the unborn baby. If you are a woman able to have children, your doctor should perform a pregnancy test before you start treatment.

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or nurse for advice before taking this medicine. Contact your doctor or nurse right away if you become pregnant while taking Voranigo.

Contraception in women and men
Voranigo should not be used in pregnancy as it could harm the unborn baby. Women who can become pregnant or men with partners who can become pregnant must use effective contraception to avoid pregnancy during treatment with Voranigo and for at least 3 months after the last dose. Voranigo may stop hormonal contraceptives (such as birth control pills, contraceptive patches or implants) from working properly. If you or your partner use a hormonal contraceptive, you must also use a barrier method (such as condoms or a diaphragm) to avoid pregnancy.

Talk to your doctor or nurse about the right methods of contraception for you and your partner.

Breast-feeding
It is not known if Voranigo passes into breast milk. Do not breast-feed while taking Voranigo and for at least 2 months after the last dose.

Fertility
Voranigo may affect your ability to have a baby. Talk to your doctor for advice before using it.

Smoking
Tell your doctor, pharmacist or nurse if you smoke as it may reduce the concentration of Voranigo in your blood.

Driving and using machines
Voranigo is not expected to affect your ability to drive or use machines.

Voranigo 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.

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

3. How to take Voranigo
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 of Voranigo in adults:
- Take **40 mg (one 40 mg tablet)** once a day.

The recommended dose for adolescents (12 years of age and older) is:
- For patients who weigh at least 40 kg, take **40 mg (one 40 mg tablet)** once a day.
- Patients who weigh less than 40 kg, take **20 mg (two 10 mg tablet)** once a day.

If you get certain side effects while you are taking Voranigo (see section 4 "Possible side effects"), your doctor may lower your dose or temporarily or permanently stop your treatment. Do not change your dose or stop taking Voranigo without talking to your doctor first.

How and when to take Voranigo
- Voranigo is taken by mouth once a day. You should try to take the medicine at the same time each day.
- Swallow the tablet whole with a glass of water. Do not split, crush or chew the tablet; you may not get the full dose you need unless you swallow a whole tablet.
- Do not eat food for at least 2 hours before and 1 hour after you take the tablet.
- If you vomit after taking your usual dose, do not take an extra dose. Take the next dose at your scheduled time.

Do not swallow the desiccant package found in the bottle.

If you take more Voranigo 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 Voranigo
Take care not to miss a dose of Voranigo. If you miss a dose by less than 6 hours, take it as soon as you remember, and then take the next dose at your scheduled time. If you miss a dose by more than 6 hours, you should skip the dose and wait to take the next dose at your scheduled time.

If you stop taking Voranigo
Do not stop taking Voranigo unless your doctor tells you to. It is important to take Voranigo every day for as long as your doctor prescribes it to you.

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.
Tell your doctor, pharmacist or nurse if you notice any of the following side effects:

Serious side effects
If you experience any serious side effects, stop taking this medicine and tell your doctor right away. Your doctor may lower your dose, pause treatment, or stop treatment completely.

Very common (may affect more than 1 in 10 people):
- Increased amount of liver enzymes, as measured in blood tests (see section 2, "Monitoring of liver function")

Other side effects
Very common (may affect more than 1 in 10 people):
- Abdominal pain (belly pain)
- Diarrhoea
- Decreased amount of blood platelets, components that help the blood to clot, as measured in blood tests; this can cause bleeding and bruising
- Tiredness

Common (may affect up to 1 in 10 people):
- Increased blood sugar levels (hyperglycaemia)
- Decreased appetite
- Low blood phosphate levels as measured in blood tests (hypophosphataemia); this can cause confusion or muscle weakness

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 website 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 Voranigo
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 bottle label and carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 Voranigo contains
The active substance is vorasidenib.
- Voranigo 10 mg: Each film-coated tablet contains 10 mg of vorasidenib (as **hemicitric acid, hemihydrate**).
- Voranigo 40 mg: Each film-coated tablet contains 40 mg of vorasidenib (as **hemicitric acid, hemihydrate**).

The other ingredients are:
- Tablet core: microcrystalline cellulose (E460), croscarmellose sodium, silicified microcrystalline cellulose, magnesium stearate (E470b) and sodium lauryl sulfate (E487)
- Film-coating: hypromellose, titanium dioxide (E171), lactose monohydrate and macrogol (E1521)
- Printing ink: black iron oxide (E172), propylene glycol (E1520) and hypromellose (E464)

See section 2 "Voranigo contains lactose" and "Voranigo contains sodium".

What Voranigo looks like and contents of the pack
10 mg film-coated tablets
- White to off-white, round tablets, imprinted with '10' on one side.

40 mg film-coated tablets
- White to off-white, oblong tablets, imprinted with '40' on one side.

Voranigo is available in a plastic bottle with child-resistant closure containing 30 film-coated tablets and 3 desiccant canisters. The bottles are packaged in a cardboard box. Each box contains 1 bottle.

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