



WHAT IS VORANIGO® VORASIDENIB?

- A targeted therapy used to treat some brain cancers.
- Prescribed and renewed by your hospital-based oncologist or cancer specialist.
- Available from hospital pharmacies on presentation of your prescription.




White to off-white film-coated tablet, dosed at:

- **10 mg**: round, with "10" on one side
- **40 mg**: oval, with "40" on one side



- Store at room temperature and keep out of the sight and reach of children.
- Do not take the tablets out of the bottle to put them in a pillbox.
- Wash your hands carefully before and after handling the tablets.
- Do not throw away opened bottles, please return them to your pharmacist.

HOW TO TAKE THIS MEDICINE

When?	= 1 dose per day at a set time, not at mealtimes (do not eat for at least 2 hours before and 1 hour after administration)
How?		Swallow the tablet(s) whole, with water, at the same time every day. Do not chew, cut, crush or dissolve them.

You can use your **patient diary*** and a **calendar** to note doses.

Do not stop taking or change how you take your treatment without consulting your doctor.

This leaflet is not a prescription, please refer to your most recent prescription.

IF YOU FORGET TO TAKE YOUR MEDICINE OR VOMIT



- **If it has been less than 6 hours since your dose was due:** take the missed dose. Take your next dose at the usual time. Record this in your patient diary*.
- **If it has been more than 6 hours since your dose was due:** do not take the missed dose. Take your next dose at the usual time, do not take a double dose. Record this in your patient diary*.
- **If you throw up,** do not take another dose. Take your next dose at the usual time, do not take a double dose. Keep a record in your patient diary*.

INTERACTION WITH OTHER MEDICINES AND OTHER INTERACTIONS



Check with your doctor or pharmacist that the medicines (prescribed or over-the-counter), other substances (foods, spices and plants, **cannabidiol**, probiotics, essential oils, food supplements, etc.) and derivative products you use are **compatible with your treatment**. The molecules they contain, their dose and how often they are taken can interact with your treatment and affect effectiveness and the occurrence of side effects.



- You and your partner must use effective methods of contraception (condoms and another method) throughout treatment **and for 3 months after the last dose**.
- Vorasidenib can stop hormonal contraceptives from working properly.
- Stop breastfeeding during treatment **and for 2 months after the last dose**.








Male and female fertility can be affected during treatment with vorasidenib.

Your doctor can tell you more about the possibility of sperm banking before starting treatment.

* Patient diary available (in French) at www.omedit-fiches-cancer.fr

WHAT SIDE EFFECTS CAN OCCUR WITH VORANIGO® VORASIDENIB?

Like all medicines, vorasidenib may cause side effects, although not everybody gets them.

Side effects	Prevention and management
 Diarrhoea	Monitor your weight. Drink sweet and/or salty beverages: water, tea with sugar, soda, soups. Avoid water containing magnesium (CONTREX®, HEPAR®), coffee, iced drinks. Eat foods low in fibre (carbohydrates, carrots, bananas); avoid food that stimulate digestion (dairy products, raw fruit/vegetables, grains, fatty foods, spices). Wash your hands regularly. Contact your doctor if you have a fever or if symptoms continue for more than 5 days.
 Unusual bleeding, bruising	Use a soft toothbrush. Do not use rectal thermometers. Do not take aspirin, anti-inflammatories (e.g. ibuprofen), or herbal products (that can increase bleeding) without consulting a healthcare professional. In case of bruising, apply cold (compress or ice pack) or a suitable cream/gel (e.g. arnica) if the skin is not broken. Contact your doctor in case of small red dots on your skin, bruising, bleeding, or blood in your urine or faeces.
 Nosebleeds	Tilt your head forward until bleeding stops and gently blow your nose to clear clots. Pinch your nostrils for 10 minutes; haemostatic products can reduce this time (packing applied after 2 minutes of compression and left in place for 30 minutes). If bleeding continues for more than 15 minutes of compression or in case of paleness, palpitations, sweating or low blood pressure: consult a doctor immediately.
 Liver toxicity	Contact your doctor if you have any symptoms suggesting liver damage: yellowing of your skin or the whites of your eyes, dark urine, loss of appetite, pain in the upper right part of your abdomen and/or sensation of weakness or intense tiredness.
 Hyperglycaemia	Possible signs of hyperglycaemia are: dry mouth, intense thirst, frequent urge to urinate, and tiredness. Regular blood glucose monitoring may be carried out. Exercise regularly. Eat a balanced diet. Suitable treatments may be prescribed as required.
 Tiredness	Eat a balanced diet. Avoid using psychostimulants (e.g. coffee, tobacco, alcohol). Take care when driving. Rest during the day, while maintaining up to moderate levels of activity. Go to bed at a regular time.
 Dizziness	Avoid stimulants (coffee, alcohol, tobacco). If you feel lightheaded, rest in a quiet place and move slowly. Speak to your doctor if you have persistent lightheadedness, unusual headaches, tinnitus or vomiting.

Only the most common side effects are listed here. For more information, read the Patient Leaflet included with your medicine or ask your doctor or pharmacist.

You can also ask your [Regional Pharmacovigilance Centre](#) and report any side effects online: signalement-sante-gouv.fr



Remember to go for the lab tests prescribed by your doctor.

WHAT TO DO IF YOU EXPERIENCE SIDE EFFECTS

- Take the medicine prescribed to counteract the side effects, as prescribed.
- Follow the preventive measures.

Useful contacts:

Note:

Contact your doctor rapidly in case of:

- Yellowing of your skin or the whites of your eyes, dark urine
- Pain in the upper right part of your abdomen
- Nosebleeds, bleeding gums, bleeding eyes, bloody urine/faeces
- Confusion or muscle weakness (hypophosphataemia)
- Any persistent or worsening side effect

