



WHAT IS TIBSOVO® IVOSIDENIB?

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




- Oval, blue tablet dosed at **250 mg**, with “250” on one side and “IVO” on the other.



- Do not store above 25°C, 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 in the two hours before or hour after taking the tablets)
How?		Swallow the tablets whole, with water, at the same time every day. Do not chew, cut, crush or dissolve them.

You can use your **medical 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 12 hours since your dose was due, take the missed dose as soon as possible. Take your next dose at the usual time. Keep a record in your medical diary*.
- If it has been more than 12 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. Keep a record in your medical 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 medical 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, including **grapefruit** and **St. John's Wort**, 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 its 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 1 month after the last dose**.
- Ivosidenib can alter the effectiveness of hormonal contraceptives.
- If you are breastfeeding: stop breastfeeding during treatment **and for 1 month after the last dose**.

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

WHAT SIDE EFFECTS CAN OCCUR WITH TIBSOVO® IVOSIDENIB?

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

Side effects	Prevention
 Rash	Use soap-free gel or a dermatological bar. Avoid hot water. Pat dry. Use moisturiser (cream or milk). Avoid sun exposure, particularly between noon and 4pm. Wear protective clothing, even under a parasol (UVA reflection). Use SPF 50+ sun cream, applied 30 minutes before exposure and reapplied every 2 hours.
 Digestive effects: diarrhoea, nausea, vomiting	Monitor your weight and remember to hydrate (1.5 to 2 L water per day). In case of diarrhoea , eat foods low in fibre (carbohydrates, carrots, bananas etc.). Avoid foods that can stimulate digestion (dairy products, raw fruit/vegetables, grains, fatty foods, spices). In case of nausea/vomiting , divide your meals into several small meals and eat slowly. Avoid fatty, fried or spicy foods, and foods that smell strongly. Avoid having an empty stomach (can worsen nausea). Drink between, rather than with, meals. Use your prescribed antiemetics if applicable.
 Pain in hands/feet, tingling, loss of feeling	Treat all cuts and injuries (blisters). Do not use hot water (check temperature with elbow); avoid getting cold. Regular exercise (walking 3 times per week) and relaxation exercises (sophrology, yoga, tai chi) can reduce pain. Prevent falling (poor lighting, objects on the floor); use ramps, hand rails and walking sticks as required. Eat a healthy, balanced diet.
 Low red blood cells, neutrophils and platelets	Low red blood cells : contact your doctor in case of paleness, shortness of breath on exertion or when resting, persistent tiredness, palpitations, dizziness or headaches. Low neutrophils : contact your doctor in case of temperature > 38°C, chills, sweating, cough, shortness of breath/pain when breathing, a burning sensation when urinating, diarrhoea accompanied by fever or any other signs suggesting infection Low platelets : contact your doctor in case of small red dots on your skin, bruising, nosebleeds, bleeding eyes or gums, or blood in your urine or faeces.
 Palpitations	Reduce stimulants (tea, coffee, alcohol, tobacco). Get enough sleep on a regular schedule. Practice relaxation techniques (sophrology, yoga, tai chi). Measure your heart rate (heart rate monitor, smartwatch or manually); keep a record. Contact your doctor if you experience malaise, dizziness, difficulty breathing or chest pain.
 Differentiation syndrome	This syndrome can appear up to 46 days after the start of treatment in patients with acute leukaemia. Symptoms include fever, difficulty breathing, cough, rash and lightheadedness. Inform your doctor if you get any of these symptoms. Keep the Patient Alert Card in the box with you and show it to any healthcare professionals you consult.
 Headache	Remember to hydrate! Eat at regular intervals, do not skip meals. Avoid tobacco and alcohol (headache triggers). Avoid going to bed and getting up late; get sufficient sleep at night.
	<i>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.</i> <i>You can also ask your Regional Pharmacovigilance Centre and report any side effects online: signalement-sante-gouv-fr</i>

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.

Contact your doctor rapidly in case of:

- Fever, cough, difficulty breathing, rash
- Lightheadedness or dizziness, irregular heartbeat
- Swollen arms or legs, rapid weight gain
- Reduced urine output
- Any persistent or worsening side effect.



Useful contacts:

Note: