Gilteritinib XOSPATA®

Patient information sheet V4, July 2024



WHAT IS XOSPATA® GILTERITINIB?

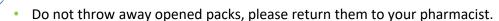
- A targeted therapy used to treat some types of leukaemia (blood cancer).
- Prescribed and renewed by your hospital-based haematologist.
- Available from community pharmacies on presentation of your prescription.



• Round, light yellow film-coated tablet, dosed at **40 mg**, with the laboratory logo and "235" on the same side



- Do not store above 30°C, and keep out of the sight and reach of children.
- Do not take the tablets out of the blister pack to put them in a pillbox.
- Wash your hands carefully before and after handling the tablets.



HOW TO TAKE THIS MEDICINE

When?	:	= 1 dose per day at a set time With or without a meal
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 you forget to take your medicine, take the missed dose as soon as possible on the same day.
 Continue your treatment at the usual time and dose the following day (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 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 6 months after the last dose for women and 4 months after the last dose for men.
- Stop breastfeeding during treatment and for 2 month after the last dose.

^{*} Patient diary available (in French) at <u>www.omedit-fiches-cancer.fr</u>

WHAT SIDE EFFECTS CAN OCCUR WITH XOSPATA® GILTERITINIB?

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

Side effects

Prevention



Digestive effects: constipation or diarrhoea, nausea Monitor your weight and remember to hydrate (1.5 to 2 L water per day). In case of constipation, eat foods rich in fibre (bran, grains, wholemeal bread, green vegetables, fruit and nuts) and exercise regularly. 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: 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.



Joint and muscle pain

Exercise regularly (suitable activities include walking and swimming). Warm up before exercising. Remember to hydrate before, during and after exerting yourself. Avoid repetitive movements and strenuous physical effort. Use a walking stick to support your joints.

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,



Palpitations

Differentiation

syndrome

difficulty breathing or chest pain.

This syndrome can appear at any time during the first 3 months of treatment. Symptoms include fever, difficulty breathing, low blood pressure, rapid weight gain, rash, dizziness or lightheadedness, swelling of arms or legs. Inform your doctor if you get any of these symptoms. Keep the Patient Alert Card in the



" 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 and get sufficient sleep at night.



Swelling of the face or limbs

compression stockings; put them on when getting up in the morning. Weigh yourself regularly. Consult your doctor if this type of swelling occurs.

Dizziness, visual disorders, tiredness, and falling are signs of low blood pressure. Stand up slowly, taking breaks. Drink sufficient quantities (at least 1.5 L per day, with 1 to 2 glasses of water before meals).

Wear compression stockings or tights. Use 1 or 2 pillows to keep your head raised in bed. Prevent falls

(fall-proof your home, stay physically active, etc.). Be careful in case of intense heat, prolonged bed rest

Eat a diet low in salt. Avoid tight clothing. If your legs swell, raise your feet when sitting. Wear



Low blood pressure

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 <u>Regional Pharmacovigilance Centre</u> and report any side effects online: <u>signalement-sante-gouv-fr</u>

or after intense physical effort. Inform your doctor if you get any symptoms.

box with you and show it to any healthcare professionals you consult.



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

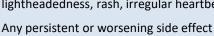
What to do if you experience side effects

Take the medicine prescribed to counteract the side effects, as prescribed.

Follow the preventive measures.

Contact your doctor rapidly in case of:

- Fever, rapid unexpected weight gain, dizziness or lightheadedness, rash, irregular heartbeat





 Note:	

Useful contacts: