Mobocertinib EXKIVITY®

Patient information sheet V1, July 2024



WHAT IS EXKIVITY® MOBOCERTINIB?

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



Opaque white capsule, dosed at 40 mg, with "MB788" printed in black on the top and "40 mg" on the bottom



- Do not store above 30°C, and keep out of the sight and reach of children.
- Do not take the capsules out of the box to put them in a pillbox.
- Wash your hands carefully before and after handling the capsules.
- Do not throw away opened packs, please return them to your pharmacist.

HOW TO TAKE THIS MEDICINE

When?	 = 1 dose per day at a set time with or without a meal
How?	Swallow the capsules 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 6 hours since your dose was due: take the missed dose. Take your next dose at the usual time. Keep a record in your medical 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. 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 week (for men) and 1 month (for women) after the last dose. Mobocertinib can stop hormonal contraceptives from working properly.
- Stop breastfeeding during treatment and for 1 week after the last dose.

Male and female fertility can be affected during treatment with mobocertinib. Your doctor can tell you more about the possibility of egg/sperm banking before starting treatment.

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



WHAT SIDE EFFECTS CAN OCCUR WITH EXKIVITY® MOBOCERTINIB?

Like all medicines, mobocertinib may cause side effects, although not everybody gets them.					
Side ef	fects	Prevention			
	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.			
	Nail conditions	Use a gentle cleansing gel to wash your hands and feet. Avoid prolonged exposure to water. Pat dry and use moisturiser. Keep your nails short (use a nail file rather than clippers). Use protective nail polish and do not use acetone-based nail polish removers (ask your pharmacist for advice). Use an antiseptic nail bath if your nails are painful, and healing cream in case of cuts.			
	Rash, itching, dry skin	Only shower/bath once per day (max. 15 minutes at 32°C). Use soap-free gel or a dermatological bar. Pat dry. Use moisturiser (cream or milk). Wear loose, light cotton clothing. Use detergent suitable for sensitive skin (no laundry softener). Drink 1.5 to 2 L water per day. In case of itching, apply cold compresses to the affected areas (do not use alcohol-based lotions). Keep your nails short (use a nail file rather than clippers).			
	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.			
	Inflamed mouth	Use a soft toothbrush and menthol-free, additive-free toothpaste. Keep your lips hydrated (ask your pharmacist for advice, particularly if you are receiving oxygen therapy. Stimulate saliva production (ice cubes, sorbets). Prefer liquids and blended foods. Avoid alcohol, tobacco, coffee and acidic, salty, irritating, spicy and crunchy foods. Use pain medication. Use your prescribed mouthwash (not mouthwash containing alcohol).			
هُ	Low red blood cells, white blood cells 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 white blood cells: 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.			
N.	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.			
555	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.			
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:					
Contact your doctor rapidly in case of: - Signs of infection (fever, cough, chills, etc.) - Shortness of breath, difficulty breathing, chest pain - Lightheadedness, dizziness, severe diarrhoea					

Any persistent or worsening side effect.