# Encorafenib BRAFTOVI®

Patient information sheet V2, December 2023



## WHAT IS BRAFTOVI® ENCORAFENIB?

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



- 50 mg capsule: orange cap and flesh-coloured body with stylised "A" on cap and "LGX 50 mg" on the body
- **75 mg** capsule: flesh-coloured cap and white body with stylised "A" on cap and "LGX 75 mg" on the body



- 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 boxes, 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 same time e	capsules whole, with water, one after another, at the very day. , cut, crush or dissolve them.	ne

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. 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.
- Stop breastfeeding during treatment.

Male fertility can be affected during treatment with encorafenib. Your doctor can tell you more about the possibility of sperm banking before starting treatment.

\*Patient diary available (in French) at <u>www.omeditbretagne.fr</u> or <u>www.omedit-paysdelaloire.fr</u>



## What side effects can occur with BRAFTOVI® encorafenib?

Prevention

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

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**Palpitations** 

Side effects

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.

Itching, dry skin

Apply cold compresses to the affected areas (do not use alcohol-based lotions). Wear loose, light cotton clothing. Use soap-free gel or a dermatological bar. Only shower/bath once per day (max. 15 minutes at 32°C). Pat dry. Use moisturiser (cream or milk). Keep your nails short (use a nail file rather than clippers). Use detergent suitable for sensitive skin (no laundry softener). Drink 2 L water per day. Contact your doctor in case of skin disorders.

Swelling, burning hands/feet Use soap-free gel or a dermatological bar. Avoid hot water. Pat dry. Use moisturiser (cream or milk). Bathe in cool water (15 min.) or apply cold compresses/ice (do not use ice in direct contact with the skin). Wear gel insoles to keep feet cool.

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



Pain in hands/feet, tingling, loss of feeling

Digestive

constipation,

diarrhoea,

effects:

floor); use ramps, hand rails and walking sticks as required. Eat a healthy, balanced diet. 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/vomiting, divide your meals



nausea, vomiting, loss of appetite

strongly. Avoid having an empty stomach (can worsen nausea). Drink between, rather than with, meals. Use your prescribed antiemetics if applicable. Remember to hydrate before, during and after exerting yourself. Exercise regularly (walking, swimming); warm up before exercising. Use a walking stick to support your joints.

into several small meals and eat slowly. Avoid fatty, fried or spicy foods, and foods that smell



Joint and/or muscle pain

Unusual

bleeding,

Avoid repetitive movements and strenuous physical effort. Use a soft toothbrush. Do not use rectal thermometers. Do not take aspirin, antiinflammatories (e.g. Ibuprofen), or herbal products (that can increase bleeding) without medical guidance: consult 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.



bruising 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>



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:

- Vision disorders
- Palpitations, increased heart rate, swollen legs
- Significant bleeding
- Changes to your skin (new wart, irritation, etc.)
- Any persistent or worsening side effect



**Useful contacts:** Note: