Dabrafenib FINLEE®

Patient information sheet
V2, December 2025

WHAT IS FINLEE® DABRAFENIB?

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

Tablet dosed at **10 mg**, dispersable, round, white to yellowish, with "D" on one side and "NVR" on the other side.

- 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 packaging or boxes, please return them to your pharmacist.

HOW TO TAKE THIS MEDICINE

When?	**……:…… and ……:……**	**= 2 doses per day, at set times** (roughly 12 hours apart), **not at mealtimes** (at least 1 hour before and 2 hours after a meal)
How?		Add still drinking water to a measuring cup: 5 mL (for 1 to 4 tablets) or 10 mL (for 5 to 15 tablets). Count out the prescribed number of tablets and add them to the cup. Mix with the handle of a stainless steel spoon until completely dissolved. Administer the oral solution (directly from the cup or with an oral syringe against the cheek) within 30 minutes of preparation. Rinse the cup with 5 mL still water and administer the residue.

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 you forget to take a dose**, take the forgotten dose if it is more than 6 hours until your next dose. If it is less than 6 hours until the next dose, do not take the forgotten dose. Take your next dose at the usual time. Keep a record 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, including **grapefruit, liquorice** 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 2 weeks after the last dose (16 weeks if combined with trametinib).** Hormonal contraceptives may be ineffective, use an alternative (barrier) method of contraception.
- Stop breastfeeding during treatment.

Male and female fertility can be affected during treatment with dabrafenib.
Your doctor can tell you more about the possibility of fertility preservation before starting treatment.

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

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WHAT SIDE EFFECTS CAN OCCUR WITH FINLEE® DABRAFENIB?

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

Side effects	*Prevention*
Rash, itching, dry skin	Only shower/bath once per day (max. 15 minutes at 32°C). Use soap-free gel or a dermatological bar. Avoid hot water. Pat dry. Use moisturiser (cream or milk). Wear loose, light cotton clothing. Use detergent suitable for sensitive skin (no laundry softener). 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: constipation or diarrhoea, abdominal pain, nausea, vomiting,	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 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.
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.
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.
Risk of infection: fever, urinary infection, nasopharyngitis (common cold)	Limit contact with people with infections. Wash your hands regularly. Disinfect all wounds thoroughly. Contact your doctor in case of temperature > 38°C, cough, shortness of breath/pain on breathing, pain when urinating/smelly urine, change in type/frequency of bowel movements (diarrhoea, constipation), or in case of redness, pain or discharge around your central line, feeding tube or urinary catheter.
Headache, tiredness	Drink sufficient quantities (1.5 to 2 L water per day) and eat healthily, at regular intervals. Avoid using psychostimulants (e.g. coffee, tobacco, alcohol). Rest during the day, while maintaining up to moderate levels of activity. Establish a sleep schedule; avoid going to bed and getting up late. Take care when driving.

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.social-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.

Contact your doctor rapidly in case of:
- Visual disorders (blurred vision, loss of vision, red eyes, etc.)
- Abdominal pain, dark urine
- Hot, red, painful arm or calf, associated with shortness of breath
- Signs of infection (fever, cough, chills, burning sensation when urinating, etc.)
- Any persistent or worsening side effect

Useful contacts:

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Note:

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