








WHAT IS BALVERSA® ERDAFITINIB?

- An anticancer drug used to treat some bladder cancers.
- Prescribed and renewed by your oncologist or cancer specialist.
- Available from hospital pharmacies on presentation of your prescription.

- 3 dosages exist in the form of round biconvex tablets:
 - **3 mg**: yellow tablet with “3” on one side and “EF” on the other
 - **4 mg**: orange tablet with “4” on one side and “EF” on the other
 - **5 mg**: brown tablet with “5” on one side and “EF” 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 box to put them in a pillbox.
-  Wash your hands carefully before and after handling the tablets.
-  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 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**. If you realise you missed yesterday's dose, 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 and plants, including **grapefruit, Seville orange juice, turmeric** 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 **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 BALVERSA® ERDAFITINIB?

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

Side effects	Prevention
 Hair loss	Use a wide tooth comb or brush with soft natural bristles. Use a gentle shampoo, rinse your hair with warm water and air dry (or at low temperatures). Avoid blow drying, rollers, perms and hair dye, which could damage your hair.
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.
 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.
 Digestive effects: constipation or diarrhoea, nausea, vomiting, loss of appetite	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.
 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).
 Low red and/or white blood cells	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
 Muscle pain	Remember to hydrate before, during and after exerting yourself. Exercise regularly (suitable activities), warm up before exercising.
 Dry eyes	Avoid dry environments (use humidifiers, ventilate rooms), smoky places and smoking. If you work on a computer, take breaks and blink regularly. Drink 1.5 to 2 L water per day, increase essential fatty acids (oily fish, rapeseed oil, leafy green vegetables).
	<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. 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.

Useful contacts:

Note:

Contact your doctor rapidly in case of:

- Signs of infection (fever, sore throat, tiredness, etc.)
- Significant mouth pain
- Eye pain, redness, decreased or blurred vision
- Any persistent or worsening side effect

