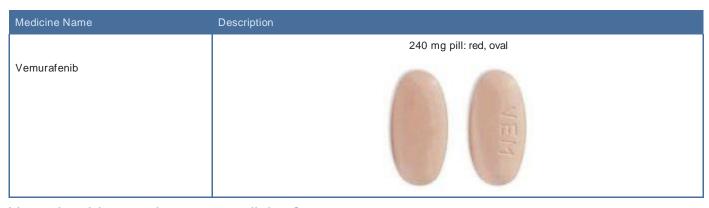


Patient Information Leaflet

Vemurafenib – ZELBORAF®

What is ZELBORAF®



How should you take your medicine?

Your doctor has determined your medicine dosage.

In your case, the dosage is as follows: mg/day, i.e. 240 mg pill(s), twice a day, every day.

Swallow whole with a glass of water; do not crush, cut, chew, or dilute the pills.

At a set time, with or without meals.

If you forgot to take a dose or in case of vomiting, do not take an additional dose but wait for the time to take the next dose.

Dosage – therapy regimen

Twice a day, at a set time, with or without meals	<u> </u>			101			101		
With no gaps	D1	D2	D3	D 4	D5	D6	D7	•••	D28

How to get the medicine supply?

This medicine is available in local pharmacies.

Getting this medicine might take time. Be careful and order the medicine in advance. Store this product in its original packaging, away from sources of heat and moisture.

What else do you need to know?

Precautions and monitoring

Laboratory tests are necessary while taking your medication (blood test to monitor blood counts, liver and kidney function, magnesium level), as well as clinical condition monitoring (ECG, dermatological and ophthalmological observations).

Using contraceptives

This drug may harm an unborn baby. During the entire treatment, you and your partner need to use effective contraception methods (condoms combined with another method).

Interactions with other medications and/or food

The occurrence of interactions between ZELBORAF® and your other treatments may have harmful consequences (reduced drug efficacy and tolerance). It is important to tell your pharmacist and doctor about all medications and/or other substances (foods, plants, probiotics, essential oils, nutritional supplements, etc.) that you are taking.

Example: While taking ZELBORAF®, it is necessary to avoid using Saint John's wort, grapefruit juice, boldo, fucus, Asian ginseng, bitter orange, passionflower, and dandelion.

What are possible side effects?

Only the most common side effects are listed below. There might be some other side effects. For additional information, refer to your medicine leaflet or seek advice from your doctor or pharmacist.



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SIDE EFFECTS			
Most common ones	Pain: in joints, in extremities, in the back, headaches Skin problems: skin rash, sun sensitivity (light sensitivity), itching, hair loss, skin induration (hyperkeratosis), tumors (benign or malignant), acne, inflammation of palms, soles of the feet, and areas of friction Digestive problems: nausea, diarrhea, vomiting, loss of appetite, constipation, taste perception disorder Abnormal lab results: abnormal liver tests, low multinuclear neutrophil count (neutropenia) Others: fatigue, dizziness, swelling of extremities, cough		
WHEN TO ALERT THE MEDIC	CAL TEAM?		
Tell medical personnel if the following conditions are present and in the absence of specific medical advice	Skin problems > Formation of a wart or a suspected lesion > Skin tenderness or a reddish bump on the skin that bleeds or does not heal Mole size or color change Significant blisters or severe peeling of the skin Digestive problems > Significant and/or rapid weight loss > Very frequent diarrhea, bowel movement over 4 times a day > Severe abdominal pain > Inability to drink for 24 hours and/or eat for about 48 hours > Bowel movements fewer than 3 times a week Pain that prevents you from doing your normal activities > Headaches > Pain or inflammation in hands and feet > Unusual and inexplicable pain in muscles Eye problems Pain in the eyes, tearing or redness, blurred vision, or light sensitivity Allergy symptoms > Rash and itching Swelling of the face, lips, tongue and/or throat causing difficulty swallowing or breathing Symptoms suggestive of cardiac problems > Shortness of breath, high palpitations		
HOW TO PREVENT SIDE EFF	ECTS?		
Weight	Regularly check your weight in case of digestive problems or swellings.		
Skin care	On hands and feet: Apply moisturizing cream or milk and/or healing cream on hands and feet (without rubbing hard). Avoid exposing hands and feet to heat (hot water). Avoid activities that cause rubbing or injury. Avoid wearing overly tight clothing, socks, or shoes Body: Opt for soft soap and moisturizer, pat skin dry. Avoid using any irritating products.		
Hair loss	Use a small amount of mild shampoo (for babies). Opt for a soft brush. Avoid washing your hair too often Avoid heat sources (hairdryer, heated curlers, hot smoothing iron), dyes, highlights, or perm.		
Protection from the sun	ESSENTIAL. Apply broad spectrum sunscreen and avoid sun exposure. Opt for long-sleeve clothing with a collar, long trousers, and hats.		
Fatigue	Opt for activities contributing to well-being, in particular adjusted and regular physical activities: walking, work in the garden, swimming, biking, sports Alternate periods of activity and rest.		
Swellings	Avoid wearing tight clothing, socks, and shoes. Put your feet in an elevated position.		
HOW TO ADAPT YOUR DIET?			
Nausea	Opt for split nutrition consisting of several light meals, liquid and cold dishes. Limit consumption of fatty, fried, and spicy foods.		
Diarrhea	Opt for a low fiber diet. It is preferable to consume starchy products, carrots, and bananas. Avoid using raw fruit and vegetables, dairy products, coffee, or alcohol. Drink more water.		
Constipation	Opt for a high fiber diet. Drink more water.		
Taste perception disorder	Opt for several small meals of warm and cold food per day. Avoid using metal kitchen utensils.		

Weight loss

Opt for a higher calorie diet and "pleasure diet".