

MEDICATION GUIDE

ZELBORAF™ (ZEL-bor-raf) (vemurafenib) tablet

Read this Medication Guide before you start taking ZELBORAF™ and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about ZELBORAF?

ZELBORAF may cause a type of skin cancer called cutaneous squamous cell carcinoma (cuSCC). CuSCC usually does not spread to other parts of the body.

Check your skin and tell your healthcare provider right away about any skin changes including a:

- new wart
- skin sore or reddish bump that bleeds or does not heal
- change in size or color of a mole

A healthcare provider should check your skin before you start taking ZELBORAF, and every two months while taking ZELBORAF to look for any new skin cancers. Your healthcare provider may continue to check your skin for six months after you stop taking ZELBORAF.

See “*What are the possible side effects of ZELBORAF?*” for more information about side effects.

What is ZELBORAF?

ZELBORAF is a prescription medicine used to treat a type of skin cancer called melanoma,

- that has spread to other parts of the body or cannot be removed by surgery, and
- that has a certain type of abnormal “BRAF” gene

It is not known if ZELBORAF is safe and effective in children under 18 years of age.

What should I tell my healthcare provider before taking ZELBORAF?

Before you start taking ZELBORAF, tell your healthcare provider if you:

- **have any heart problems, including a condition called long QT syndrome**
- **have liver or kidney problems**
- **have been told that you have low blood levels of potassium, calcium, or magnesium**
- **plan to have surgery, dental or other medical procedures**
- **have any other medical conditions**
- **are pregnant or plan to become pregnant.** ZELBORAF may harm your unborn baby.
 - Females who are able to become pregnant, and males who take ZELBORAF should use birth control during treatment and for 2 months after stopping ZELBORAF.
 - Talk to your healthcare provider about birth control methods that may be right for you.
 - Tell your healthcare provider right away if you become pregnant during treatment with ZELBORAF.
- **are breastfeeding or plan to breastfeed.** It is not known if ZELBORAF passes into your breast milk. You and your healthcare provider should decide if you will take ZELBORAF or breastfeed. You should not do both.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Especially, tell your healthcare provider if you take:

- the blood thinner warfarin sodium (Coumadin, Jantoven)

- antifungal medicines, such as ketoconazole (Nizoral), itraconazole (Sporanox, Onmel), or voriconazole (Vfend)
- certain antibiotic medicines, such as telithromycin (Ketek), clarithromycin (Biaxin, Biaxin XL), rifampin (Rifater, Rifimate, Rimactane, Rifadin), rifabutin (Mycobutin), rifapentine (Prifin)
- HIV medicines, such as atazanavir sulfate (Reyataz), saquinavir mesylate (Invirase), ritonavir (Kaletra), indinavir sulfate (Crixivan), nelfinavir mesylate (Viracept)
- seizure medicines, such as phenytoin (Dilantin-125, Dilantin, phenobarbital (Solfoton), or carbamazepine (Carbitrol, Equetro, Tegretol, Tegretol-XR, Teril, Eptol)
- the anti-depressant medicine nafazodone hydrochloride
- medicines to treat irregular heart beat

Know the medicines you take. Keep a list to show your healthcare provider and pharmacist when you get a new medicine.

How should I take ZELBORAF?

- Take ZELBORAF exactly as your healthcare provider tells you. Do not change your dose or stop ZELBORAF unless your healthcare provider tells you.
- ZELBORAF is taken in the morning and in the evening, about 12 hours apart.
- Take ZELBORAF with or without a meal.
- Swallow the tablets whole with a glass of water. Do not chew or crush ZELBORAF tablets.
- If you miss a dose, take it as soon as you remember. If it is within 4 hours of your next scheduled dose, just take your next dose at your regular time. Do not make up for the missed dose.
- Do not take 2 doses of ZELBORAF at the same time.
- If you take too much ZELBORAF, call your healthcare provider right away.

What should I avoid while taking ZELBORAF?

Avoid sunlight while you are taking ZELBORAF. ZELBORAF can make your skin sensitive to sunlight. You may burn more easily and get severe sunburns. To help protect against sunburn:

- When you go outside, wear clothes that protect your skin, including head, face, hands, arms, and legs.
- Use lip balm and a broad-spectrum sunscreen with SPF 30 or higher.

What are the possible side effects of ZELBORAF?

ZELBORAF may cause serious side effects, including:

- See *“What is the most important information I should know about ZELBORAF?”*
- **Allergic reactions can happen while taking your ZELBORAF, and may be severe.** Stop taking ZELBORAF and get medical help right away if you have any of these symptoms of an allergic reaction:
 - get a rash or redness all over your body
 - feel faint
 - have trouble breathing or swallowing
 - have throat tightness or hoarseness
 - have a fast heartbeat
 - have swelling of the face, lips or tongue
- **Severe skin reactions. Stop taking ZELBORAF and call your healthcare provider right away if you get a skin rash with any of the following symptoms because you may have a severe skin reaction:**
 - blisters on your skin
 - blisters or sores in your mouth
 - peeling of your skin
 - fever
 - redness or swelling of your face, hands, or soles of your feet
- **Changes in the electrical activity of your heart called QT prolongation. QT prolongation can cause irregular heartbeats that can be life-threatening.** Your healthcare provider should do tests

before you start taking ZELBORAF, if your dose changes, at certain other times during treatment, and after you stop treatment with ZELBORAF, to check the levels of potassium, magnesium, and calcium in your blood, and check the electrical activity of your heart with an ECG.

Tell your healthcare provider right away if you feel faint, lightheaded, dizzy or feel your heart beating irregularly or fast while taking ZELBORAF. These may be symptoms related to QT prolongation.

- **Abnormal liver function tests.** Your healthcare provider should do blood tests to check your liver function before you start taking ZELBORAF and during treatment. Tell your healthcare provider right away if you get any of these symptoms of a liver problem during treatment:
 - your skin or the whites of your eyes turn yellow
 - you feel tired
 - your urine turns dark or brown (tea color)
 - you have nausea or vomiting
 - you do not want to eat
 - pain on the right side of your stomach
- **Eye problems.** You should have your eyes examined before and while you are taking your ZELBORAF. Tell your healthcare provider right away if you get these symptoms during treatment with ZELBORAF:
 - eye pain, swelling, or redness,
 - blurred vision or other vision changes during treatment with ZELBORAF
- **New melanoma lesions.** You may develop new melanoma lesions while taking ZELBORAF. Check your skin and tell your healthcare provider right away about any skin changes.

The most common side effects of ZELBORAF include:

- joint pain
- rash (see “Severe skin reactions” above)
- hair loss
- tiredness
- sunburn or sun sensitivity
- nausea
- itching
- warts

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all possible side effects of ZELBORAF. For more information about side effects, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

You may also report side effects to Genentech at 1-888-835-2555.

How should I store ZELBORAF?

- Store ZELBORAF at room temperature between 68°F to 77°F (20°C to 25°C).
- Store ZELBORAF in the original container with the lid tightly closed.
- Ask your healthcare provider or pharmacist how to safely throw away (dispose of) any unused or expired ZELBORAF.

Keep ZELBORAF and all medicine out of the reach of children.

General information about ZELBORAF

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ZELBORAF for a condition for which it was not prescribed. Do not give ZELBORAF to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about ZELBORAF. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about ZELBORAF that is written for health professionals.

For more information, call Genentech at 1-888-835-2555.

What are the ingredients in ZELBORAF?

Active ingredient: vemurafenib

Inactive ingredients: hypromellose acetate succinate, croscarmellose sodium, colloidal silicon dioxide, magnesium stearate, hydroxypropyl cellulose.

Coating: pinkish white: poly(vinyl alcohol), titanium dioxide, polyethylene glycol 3350, talc, and iron oxide red.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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