MEDICATION GUIDE
ZELBORAF® (ZEL-bor-raf)
(vemurafenib)
tablet

What is the most important information I should know about ZELBORAF?
ZELBORAF can cause serious side effects, including:
Risk of new cancers. ZELBORAF may cause certain types of skin cancer called cutaneous squamous cell carcinoma (cuSCC) and keratoacanthoma. New melanoma lesions have occurred in people who take ZELBORAF. ZELBORAF may also cause another type of cancer called non-cutaneous squamous cell carcinoma (non-cuSCC). Talk with your healthcare provider about your risk for these cancers.
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

Your healthcare provider should check your skin before you start taking ZELBORAF, and every 2 months during treatment with ZELBORAF, to look for any new skin cancers. Your healthcare provider may continue to check your skin for 6 months after you stop taking ZELBORAF.

Your healthcare provider should also check for cancers that may not occur on the skin. Tell your healthcare provider about any new symptoms that you get while taking ZELBORAF.

Other blood cell cancers have happened in some people with Erdheim-Chester Disease (ECD) including those who take ZELBORAF. If you have other blood cell cancers and take ZELBORAF for ECD, your healthcare provider will monitor your blood cancer through routine blood tests.

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
  - has a certain type of abnormal "BRAF" gene.

ZELBORAF is not used to treat melanoma with a normal BRAF gene.
Your healthcare provider will perform a test to make sure that ZELBORAF is right for you.

- a type of blood cell cancer called Erdheim-Chester Disease (ECD) that:
  - can affect body tissues and organs, and
  - 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.

Before you take ZELBORAF, tell your healthcare provider about all of your medical conditions, including if you:

- have any heart problems, including a condition called long QT syndromes
- have liver or kidney problems
- have had or are planning to receive radiation therapy
- have been told that you have low blood levels of potassium, calcium, or magnesium
- are pregnant or plan to become pregnant. ZELBORAF can harm your unborn baby.
  - Females who are able to become pregnant should use effective birth control during treatment with ZELBORAF and for 2 weeks after the final dose of 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 or think you are pregnant during treatment with ZELBORAF.
- are breastfeeding or plan to breastfeed. It is not known if ZELBORAF passes into your breast milk. Do not breastfeed during treatment with ZELBORAF and for 2 weeks after the final dose of ZELBORAF. Talk to your healthcare provider about the best way to feed your baby during this time.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Know the medicines you take. Keep a list of them 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 taking ZELBORAF unless your healthcare provider tells you to.
- Take ZELBORAF every 12 hours with or without a meal.
- Do not crush or chew ZELBORAF tablets.
- Do not take an additional dose of ZELBORAF if you vomit after taking your scheduled dose. Take your next dose at your regular time.
- If you miss a dose of ZELBORAF, 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.
- If you take too much ZELBORAF, call your healthcare provider or go the nearest hospital emergency room right away.

What should I avoid while taking ZELBORAF?

Avoid sunlight during treatment with 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 your 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 ZELBORAF and can be severe.** Stop taking ZELBORAF and get medical help right away if you get any of these symptoms of an allergic reaction:
  - rash or redness all over your body
  - trouble breathing or swallowing
  - swelling of the face, lips, or tongue
  - throat tightness or hoarseness
  - feel faint
  - a fast heartbeat
- **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 and during your treatment with ZELBORAF to check the electrical activity of your heart and your body salts (electrolytes). 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.
- **Liver injury.** 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:
  - yellowing of your skin or the white part of your eyes
  - dark or brown (tea color) urine
  - nausea or vomiting
  - loss of appetite
  - pain on the right side of your stomach
- **Eye problems.** Tell your healthcare provider right away if you get any of these symptoms during treatment with ZELBORAF:
  - eye pain, swelling, or redness
  - blurred vision or other vision changes
- **Worsening side effects from radiation treatment that can sometimes be severe or lead to death.** Tell your healthcare provider if you have had or are planning to receive radiation therapy.
- **Kidney injury**. Your healthcare provider should do blood tests to check your kidney function before you start taking ZELBORAF and during treatment.
- **Connective tissue disorders.** Tell your healthcare provider if you develop an unusual thickening of the palms of your hands along with tightening of the fingers inward or any unusual thickening of the soles of your feet which may be painful.

The most common side effects of ZELBORAF in melanoma include:

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

The most common side effects of ZELBORAF in Erdheim-Chester Disease include:

- joint pain
- rash
- warts
- tiredness
- hair loss
- QT prolongation (**see** "**Changes in the electrical activity of your heart called QT prolongation" above)**

These are not all the possible side effects of ZELBORAF.

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 the safe and effective use of 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. You can ask your healthcare provider or pharmacist for information about ZELBORAF that is written for health professionals.

What are the ingredients in ZELBORAF?

Active ingredient: vemurafenib

Inactive ingredients:

Tablet Core: hypromellose acetate succinate, croscarmellose sodium, colloidal silicon dioxide, magnesium stearate, and hydroxypropyl cellulose.

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

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