

333 **MEDICATION GUIDE**
334 **ERIVEDGE™ (EH-rih-vej)**
335 (vismodegib)
336 capsule
337

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

341
342 **What is the most important information I should know about ERIVEDGE?**

343 **ERIVEDGE can cause your baby to die before it is born (be stillborn) or cause your baby to**
344 **have severe birth defects.**

345 For females who can become pregnant:

- 346 • You should talk with your healthcare provider about the risks of ERIVEDGE to your unborn
347 child.
- 348 • Your healthcare provider should do a pregnancy test within 7 days before you start taking
349 ERIVEDGE to find out if you are pregnant.
- 350 • In order to avoid pregnancy, you should start using highly effective birth control before you
351 start ERIVEDGE, and continue to use highly effective birth control during treatment, and for
352 7 months after your last dose of ERIVEDGE. Talk with your healthcare provider about what
353 birth control method is right for you during this time.
- 354 • Talk to your healthcare provider right away if you have unprotected sex or if you think that
355 your birth control has failed.
- 356 • Tell your healthcare provider right away if you become pregnant or think that you may be
357 pregnant.

358 For males:

- 359 • You should always use a condom with a spermicide, even if you have had a vasectomy,
360 during sex with female partners while you are taking ERIVEDGE and for 2 months after
361 your last dose to protect your female partner from being exposed to ERIVEDGE.
- 362 • Tell your healthcare provider right away if your partner becomes pregnant or thinks she is
363 pregnant while you are taking ERIVEDGE.

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365 **Exposure to ERIVEDGE during pregnancy:**

If you think that you or your female partner may have been exposed to ERIVEDGE during pregnancy, talk to your healthcare provider right away. Pregnant women are encouraged to participate in a program that collects information about exposure to ERIVEDGE during pregnancy, and the effects on the mother and her unborn child. This program is called the ERIVEDGE pregnancy pharmacovigilance program. You may participate in this program by calling the Genentech Adverse Event Line at 1-888-835-2555.

366 **What is ERIVEDGE?**

367 ERIVEDGE is a prescription medicine used to treat adults with a type of skin cancer, called basal
368 cell carcinoma, that has spread to other parts of the body or that has come back after surgery or that
369 your healthcare provider decides cannot be treated with surgery or radiation.

370 It is not known if ERIVEDGE is safe and effective in children.

371

372 **What should I tell my healthcare provider before taking ERIVEDGE?**

373 **Before taking ERIVEDGE, tell your healthcare provider if you:**

- 374 • **are pregnant or plan to become pregnant.** See “**What is the most important**
375 **information I should know about ERIVEDGE?**”
- 376 • **are breastfeeding or plan to breastfeed.** It is not known if ERIVEDGE passes into your
377 breast milk. You and your healthcare provider should decide if you will take ERIVEDGE or
378 breastfeed. You should not do both.

379 **Tell your healthcare provider about all the medicines you take,** including prescription and
380 non-prescription medicines, vitamins, and herbal supplements.

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

383

384 **How should I take ERIVEDGE?**

- 385 • Take ERIVEDGE exactly as your healthcare provider tells you.
- 386 • You can take ERIVEDGE with or without food.
- 387 • Swallow ERIVEDGE capsules whole. Do not open or crush the capsules.
- 388 • Take ERIVEDGE one time each day.
- 389 • If you miss a dose, skip the missed dose. Just take your next scheduled dose.

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391 **What should I avoid while taking ERIVEDGE?**

- 392 • Do not donate blood or blood products while you are taking ERIVEDGE and for 7 months
393 after your last dose.

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395 **What are the possible side effects of ERIVEDGE?**

396 **ERIVEDGE can cause serious side effects, including:**

- 397 • See “**What is the most important information I should know about ERIVEDGE?**”

398 The most common side effects of ERIVEDGE are:

- 399 • muscle spasms
- 400 • hair loss
- 401 • change in how things taste or loss of taste
- 402 • weight loss
- 403 • tiredness
- 404 • nausea
- 405 • diarrhea

- 406 • decreased appetite
- 407 • constipation
- 408 • vomiting
- 409 • joint aches

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

411 These are not all the possible side effects of ERIVEDGE. For more information, ask your healthcare
412 provider or pharmacist.

413 Call your doctor for medical advice about side effects. You may report side effects to FDA at
414 1-800-FDA-1088.

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

416

417 **How should I store ERIVEDGE?**

- 418 • Store ERIVEDGE at room temperature between 68°F to 77°F (20°C to 25°C).

419 **Keep ERIVEDGE and all medicines out of the reach of children.**

420

421 **General information about ERIVEDGE**

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

425 This Medication Guide summarizes the most important information about ERIVEDGE. If you
426 would like more information, ask your health care provider. You can ask your healthcare provider
427 or pharmacist for the FDA-approved information about ERIVEDGE that is written for healthcare
428 professionals.

429 For more information, call 1-855-737-4833 or visit www.erivedge.com

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431 **What are the ingredients in ERIVEDGE?**

432 Active ingredient: vismodegib

433 Inactive ingredients: microcrystalline cellulose, lactose monohydrate, sodium lauryl sulfate,
434 povidone, sodium starch glycolate, talc, magnesium stearate (non bovine). The capsule shell
435 contains gelatin, titanium dioxide, red iron oxide, and black iron oxide. The black printing ink
436 contains shellac and black iron oxide.

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