

455 **MEDICATION GUIDE**
456 **TAFINLAR® (TAFF-in-lar)**
457 **(dabrafenib)**
458 **capsules**

459
460 **What is the most important information I should know about TAFINLAR?**

461 **TAFINLAR may cause serious side effects, including:**

462 **Risk of new cancers. TAFINLAR may cause new cancers, including**
463 **cutaneous squamous cell carcinoma (cuSCC) that can spread to other parts**
464 **of the body. Talk with your healthcare provider about your risk for**
465 **developing skin cancers.**

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

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

471 Your healthcare provider should check your skin before you start taking TAFINLAR,
472 and every two months while taking TAFINLAR to look for any new skin cancers.

473 Your healthcare provider may continue to check your skin for six months after you
474 stop taking TAFINLAR.

475 See "What are the possible side effects of TAFINLAR?" for more information about
476 side effects.

477
478 **What is TAFINLAR?**

479 TAFINLAR is a prescription medicine used to treat a type of skin cancer called
480 melanoma:

- 481 • that has spread to other parts of the body or cannot be removed by surgery,
482 and
- 483 • that has a certain type of abnormal "BRAF" gene.

484
485 Your healthcare provider will perform a test to make sure that TAFINLAR is right for
486 you.

487 TAFINLAR is not used to treat people with a type of skin cancer called wild-type
488 BRAF melanoma.

489 It is not known if TAFINLAR is safe and effective in children.
490

491 **What should I tell my healthcare provider before taking TAFINLAR?**

492 **Before you start taking TAFINLAR, tell your healthcare provider if you:**

- 493 • have liver or kidney problems
- 494 • have diabetes
- 495 • plan to have surgery, dental, or other medical procedures
- 496 • have a deficiency of the glucose-6-phosphate dehydrogenase (G6PD) enzyme
- 497 • have any other medical conditions
- 498 • are pregnant or plan to become pregnant. TAFINLAR can harm your unborn
499 baby.
- 500 ○ Females who are able to become pregnant should use birth control during
501 treatment and for 4 weeks after stopping TAFINLAR.
 - 502 ○ Birth control using hormones (such as birth control pills, injections, or
503 patches) may not work as well while you are taking TAFINLAR. You should
504 use another effective method of birth control while taking TAFINLAR. Talk
505 to your healthcare provider about birth control methods that may be right
506 for you.
 - 507 ○ Tell your healthcare provider right away if you become pregnant during
508 treatment with TAFINLAR.
- 509 • are breastfeeding or plan to breastfeed. It is not known if TAFINLAR passes into
510 your breast milk. You and your healthcare provider should decide if you will take
511 TAFINLAR or breastfeed. You should not do both.

512

513 TAFINLAR may cause lower sperm counts in men. This could affect the ability to
514 father a child. Talk to your healthcare provider if this is a concern for you. Talk to
515 your healthcare provider about family planning options that might be right for you.
516

517 **Tell your healthcare provider about all the medicines you take** including
518 prescription and over-the-counter medicines, vitamins, and herbal supplements.
519 TAFINLAR and certain other medicines can affect each other, causing side effects.
520 TAFINLAR may affect the way other medicines work, and other medicines may

521 affect how TAFINLAR works. You can ask your pharmacist for a list of medicines
522 that may interact with TAFINLAR.

523

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

526

527 **How should I take TAFINLAR?**

528 • Take TAFINLAR exactly as your healthcare provider tells you. Do not change
529 your dose or stop TAFINLAR unless your healthcare provider tells you.

530 • Take TAFINLAR 2 times a day, about 12 hours apart.

531 • Take TAFINLAR at least 1 hour before or 2 hours after a meal.

532 • Do not open, crush, or break TAFINLAR capsules.

533 • If you miss a dose, take it as soon as you remember. If it is within 6 hours of
534 your next scheduled dose, just take your next dose at your regular time. Do not
535 make up for the missed dose. If you take too much TAFINLAR, call your
536 healthcare provider or go to the nearest hospital emergency room right away.

537

538 **What are the possible side effects of TAFINLAR?**

539 **TAFINLAR may cause serious side effects, including:**

540 • **See “What is the most important information I should know about**
541 **TAFINLAR?”**

542 • **Fever.** TAFINLAR can cause fever, including severe fever. In some cases, too
543 much fluid loss (dehydration), low blood pressure, dizziness, or kidney problems
544 may happen with the fever. Tell your healthcare provider right away if you get a
545 fever while taking TAFINLAR.

546 • **Blood sugar problems.** Some people may develop high blood sugar or
547 worsening diabetes during treatment with TAFINLAR. If you are diabetic, your
548 healthcare provider will check your blood sugar levels before and during
549 treatment with TAFINLAR. Tell your healthcare provider if you have any of the
550 following symptoms of high blood sugar:

551 o increased thirst

552 o urinating more often than normal

553 o your breath smells like fruit

554

555 • **Eye problems.** You should have your eyes examined before and while you are
556 taking TAFINLAR. Tell your healthcare provider right away if you get these
557 symptoms during treatment with TAFINLAR:

- 558 ○ eye pain, swelling, or redness
- 559 ○ blurred vision or other vision changes during treatment with TAFINLAR

560

561 The most common side effects of TAFINLAR include:

- 562 • thickening of the outer layers of the skin
- 563 • headache
- 564 • joint aches
- 565 • warts
- 566 • hair loss
- 567 • redness, swelling, peeling, or tenderness of hands or feet
- 568
- 569

570

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

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

575 Call your doctor for medical advice about side effects. You may report side effects
576 to FDA at 1-800-FDA-1088. You may also report side effects to GSK at 1-888-825-
577 5249.

578

579 **How should I store TAFINLAR?**

- 580 • Store TAFINLAR at room temperature, between 68°F to 77°F (20°C to 25°C).
- 581 • Ask your healthcare provider or pharmacist how to safely throw away TAFINLAR
582 that is out of date or no longer needed.

583

584 **Keep TAFINLAR and all medicine out of the reach of children.**

585

586 **General information about TAFINLAR**

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

591 If you would like more information, talk with your healthcare provider. You can ask
592 your healthcare provider or pharmacist for information about TAFINLAR that is
593 written for health professionals.

594 For more information, call GlaxoSmithKline at 1-888-825-5249 or go to
595 www.TAFINLAR.com.

596

597 **What are the ingredients in TAFINLAR?**

598 Active ingredient: dabrafenib

599 Inactive ingredients: colloidal silicon dioxide, magnesium stearate, microcrystalline
600 cellulose

601 Capsule shells contain: hypromellose, red iron oxide (E172), titanium dioxide
602 (E171).

603

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

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607 TAFINLAR is a registered trademark of the GlaxoSmithKline group of companies.

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