MEDICATION GUIDE
TAFINLAR® (TAFF-in-lar)
(dabrafenib)
capsules

If your healthcare provider prescribes TAFINLAR for you to be taken with trametinib, also read the Patient Information leaflet that comes with trametinib.

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

TAFINLAR may cause serious side effects, including the risk of new cancers:

TAFINLAR, when used alone or with trametinib, may cause a type of skin cancer, called cutaneous squamous cell carcinoma (cuSCC). New melanoma lesions may happen in people who take TAFINLAR alone or with trametinib.

TAFINLAR with trametinib, may cause new cancers including basal cell carcinoma.

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 treatment with TAFINLAR, every two months during treatment with TAFINLAR, and for up to 6 months after you stop taking TAFINLAR to look for any new skin cancers.

Your healthcare provider should also check for cancers that may not occur on the skin. Tell your healthcare provider about any new symptoms that develop during treatment with TAFINLAR.

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

What is TAFINLAR?

TAFINLAR is a prescription medicine used alone or with a medicine called trametinib, to treat people with 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.

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

TAFINLAR alone or with trametinib is not used to treat people with a type of skin cancer called wild-type BRAF melanoma.

It is not known if TAFINLAR alone or TAFINLAR with trametinib is safe and effective in children.

What should I tell my healthcare provider before taking TAFINLAR?

Before you take TAFINLAR, tell your healthcare provider if you:

- have had bleeding problems
- have heart problems
- have eye problems
- have liver or kidney problems
- have diabetes

- plan to have surgery, dental, or other medical procedures
- have a deficiency of the glucose-6-phosphate dehydrogenase (G6PD) enzyme
- have any other medical conditions
- are pregnant or plan to become pregnant. TAFINLAR can harm your unborn baby.
  - Females who are able to become pregnant should use birth control (contraception) during treatment with TAFINLAR, and for 2 weeks after the last dose of TAFINLAR alone, **or** for 4 months after the last dose when taking TAFINLAR with trametinib.
  - Birth control methods that contain hormones (such as birth control pills, injections, or patches) may not work as well during treatment with TAFINLAR alone or TAFINLAR and trametinib. You should use another effective method of birth control during treatment with TAFINLAR alone or TAFINLAR and trametinib.
  - Talk to your healthcare provider about birth control methods that may be right for you during this time.
  - Tell your healthcare provider right away if you become pregnant or think you might be pregnant during treatment with TAFINLAR alone or TAFINLAR and trametinib.
- are breastfeeding or plan to breastfeed. It is not known if TAFINLAR passes into your breast milk.
  - Do not breastfeed during treatment and for 2 weeks after your last dose of TAFINLAR alone, **or** for 4 months after your last dose of TAFINLAR with trametinib. 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. TAFINLAR and certain other medicines can affect each other, causing side effects. TAFINLAR may affect the way other medicines work, and other medicines may affect how TAFINLAR works. You can ask your pharmacist for a list of medicines that may interact with TAFINLAR.

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 TAFINLAR?

- Take TAFINLAR exactly as your healthcare provider tells you. Do not change your dose or stop TAFINLAR unless your healthcare provider tells you.
- Take TAFINLAR 2 times a day, about 12 hours apart.
- Take TAFINLAR at least 1 hour before or 2 hours after a meal.
- Do not open, crush, or break TAFINLAR capsules.
- If you miss a dose of TAFINLAR, take it as soon as you remember. But, if it is within 6 hours of your next scheduled dose, just take your next dose at your regular time. Do not make up for the missed dose.

What are the possible side effects of TAFINLAR?

TAFINLAR may cause serious side effects, including:

- **See "What is the most important information I should know about TAFINLAR?"**
- TAFINLAR, when taken with trametinib, can cause serious bleeding problems, especially in your brain or stomach, and can lead to death. Call your healthcare provider and get medical help right away if you have any signs of bleeding, including:
  - headaches, dizziness, or feeling weak

- cough up blood or blood clots
- vomit blood or your vomit looks like “coffee grounds”
- red or black stool that looks like tar

- **heart problems**, including heart failure. Your healthcare provider should check your heart function before and during treatment with TAFINLAR. Call your healthcare provider right away if you have any of the following signs and symptoms of a heart problem:
  - feeling like your heart is pounding or racing
  - shortness of breath
  - swelling of your ankles or feet
  - feeling lightheaded
- **eye problems**. TAFINLAR, when taken alone or with trametinib, can cause severe eye problems that can lead to blindness. Call your healthcare provider right away if you get these symptoms of eye problems:
  - blurred vision, loss of vision, or other vision changes
  - see color dots
  - halo (see blurred outline around objects)
  - eye pain, swelling, or redness
- **fever**. Fever is common during treatment with TAFINLAR alone or with trametinib, but may also be serious. When taking TAFINLAR with trametinib, fever may happen more often or may be more severe. In some cases, chills or shaking chills, too much fluid loss (dehydration), low blood pressure, dizziness, or kidney problems may happen with the fever. Call your healthcare provider right away if you get a fever during treatment with TAFINLAR.
- **skin reactions**. Rash is a common side effect of TAFINLAR when taken alone, or with trametinib. TAFINLAR, when taken alone or with trametinib, can also cause other skin reactions. In some cases these rashes and other skin reactions can be severe, and may need to be treated in a hospital. Call your healthcare provider if you get any of the following symptoms:
  - skin rash that bothers you or does not go away
  - acne
  - redness, swelling, peeling, or tenderness of hands or feet
  - skin redness
- **increased blood sugar (hyperglycemia)**. Some people may develop high blood sugar or worsening diabetes during treatment with TAFINLAR, alone or with trametinib. If you are diabetic, your healthcare provider should check your blood sugar levels closely during treatment with TAFINLAR alone or with trametinib. Your diabetes medicine may need to be changed. Tell your healthcare provider if you have any of the following symptoms of severe high blood sugar:
  - increased thirst
  - urinating more often than normal, or urinating an increased amount of urine
- TAFINLAR may cause healthy red blood cells to break down too early in people with G6PD deficiency. This may lead to a type of anemia called hemolytic anemia where the body does not have enough healthy red blood cells. Tell your healthcare provider if you have any of the following signs or symptoms:
  - yellow skin (jaundice)
  - weakness or dizziness

- shortness of breath

The most common side effects of TAFINLAR alone or with trametinib include:

- thickening of the outer layers of the skin
- headache
- joint aches
- cough
- warts
- hair loss
- redness, swelling, peeling, or tenderness of hands or feet

TAFINLAR may cause fertility problems in females. This could affect your ability to become pregnant. Talk to your healthcare provider if this is a concern for you.

TAFINLAR may cause lower sperm counts in males. This could affect the ability to father a child. Talk to your healthcare provider if this is a concern for you.

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

These are not all of the possible side effects of TAFINLAR. 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 Novartis Pharmaceuticals Corporation at 1-888-669-6682.

How should I store TAFINLAR?

- Store TAFINLAR at room temperature, between 68°F to 77°F (20°C to 25°C).

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

General information about the safe and effective use of TAFINLAR

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use TAFINLAR for a condition for which it was not prescribed. Do not give TAFINLAR 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 TAFINLAR that is written for health professionals.

What are the ingredients in TAFINLAR?

Active ingredient: dabrafenib

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

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

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

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