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

TAFINLAR may cause serious side effects, including:

Risk of new cancers. TAFINLAR may cause new cancers, including cutaneous squamous cell carcinoma (cuSCC) that can spread to other parts of the body. Talk with your healthcare provider about your risk for developing skin 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 TAFINLAR, and every two months while taking TAFINLAR to look for any new skin cancers. Your healthcare provider may continue to check your skin for six months after you stop taking 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 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.

Your healthcare provider will perform a test to make sure that TAFINLAR is right for you.
TAFINLAR is not used to treat people with a type of skin cancer called wild-type BRAF melanoma.

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

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

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

- 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 during treatment and for 4 weeks after stopping TAFINLAR.
  - Birth control using hormones (such as birth control pills, injections, or patches) may not work as well while you are taking TAFINLAR. You should use another effective method of birth control while taking TAFINLAR. 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 TAFINLAR.
- are breastfeeding or plan to breastfeed. It is not known if TAFINLAR passes into your breast milk. You and your healthcare provider should decide if you will take TAFINLAR or breastfeed. You should not do both.

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

**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, take it as soon as you remember. 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. If you take too much TAFINLAR, call your healthcare provider or go to the nearest hospital emergency room right away.

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?”
- Fever. TAFINLAR can cause fever, including severe fever. In some cases, too much fluid loss (dehydration), low blood pressure, dizziness, or kidney problems may happen with the fever. Tell your healthcare provider right away if you get a fever while taking TAFINLAR.
- Blood sugar problems. Some people may develop high blood sugar or worsening diabetes during treatment with TAFINLAR. If you are diabetic, your healthcare provider will check your blood sugar levels before and during treatment with TAFINLAR. Tell your healthcare provider if you have any of the following symptoms of high blood sugar:
  - increased thirst
  - urinating more often than normal
  - your breath smells like fruit
Eye problems. You should have your eyes examined before and while you are taking TAFINLAR. Tell your healthcare provider right away if you get these symptoms during treatment with TAFINLAR:

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

The most common side effects of TAFINLAR include:

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

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 GSK at 1-888-825-5249.

How should I store TAFINLAR?

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

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

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

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

What are the ingredients in TAFINLAR?

Active ingredient: dabrafenib

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

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

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

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