

UNDERSTANDING SIDE EFFECTS TO HELP STAY ON TRACK

Learn about the possible side effects associated with TAFINLAR + MEKINIST and **be ready** to manage them.

APPROVED USES

TAFINLAR and MEKINIST are prescription medicines that can be used in combination to treat people with a type of skin cancer called melanoma:

- that has spread to other parts of the body (metastatic) or cannot be removed by surgery (unresectable), and
- that has a certain type of abnormal “BRAF” (V600E or V600K mutation-positive) gene

TAFINLAR and MEKINIST are prescription medicines that can be used in combination to help prevent melanoma that has a certain type of abnormal “BRAF” gene from coming back after the cancer has been removed by surgery.

TAFINLAR, in combination with MEKINIST, is not for use in treating people with wild-type BRAF melanoma. MEKINIST should not be used to treat people who already have received a BRAF inhibitor for treatment of their melanoma and it did not work or is no longer working.

Your health care provider will perform a test to make sure that TAFINLAR and MEKINIST in combination is right for you.

It is not known if TAFINLAR, in combination with MEKINIST, is safe and effective in children younger than 1 years of age. It is not known if TAFINLAR used alone is safe and effective in children.

Please see additional Important Safety Information throughout this brochure and on pages [6 to 9](#).

Please [click here](#) for full Prescribing Information for TAFINLAR, including Medication Guide, and [click here](#) for full Prescribing Information for MEKINIST, including Patient Information.

UNDERSTANDING SIDE EFFECTS

The best way for you, your support system, and your health care provider to **be ready** for some of the most common side effects of treatment with TAFINLAR + MEKINIST is to know what to expect and what to do if you experience them.

Serious side effects

For a complete list of potential side effects, please see “Important Safety Information” on [pages 6-9](#). Serious side effects associated with TAFINLAR + MEKINIST include risk of new skin cancers, bleeding problems, inflammation of the intestines or tears (perforation) of the stomach or intestines, blood clots, heart problems, eye problems, lung or breathing problems, fever, serious skin reactions, increased blood sugar, a type of anemia called hemolytic anemia and hemophagocytic lymphohistiocytosis. Talk to your health care provider right away if you experience any side effects. Your health care provider may choose to modify, interrupt, or discontinue your treatment.

Managing common side effects

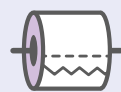
If you’re experiencing any of the following symptoms, your health care provider might recommend:



Fever

- Drinking liquids (for example, water, soups, or ice pops)
- Getting plenty of rest
- Placing a cold cloth on your forehead if you feel hot
- Using over-the-counter antifever medicines

Please see pages 4 and 5 for more information about fever.



Nausea, diarrhea, and vomiting

- A specific diet plan
- Increasing fluids
- Decreasing greasy and/or fried foods and foods containing dairy



Tiredness

- Exercise, which can be helpful with cancer-related fatigue
- A regular routine of activity and rest, including eating



Rash

- Limiting exposure to the sun
- Using a hypoallergenic moisturizing cream to soothe affected areas



Headache

- Over-the-counter pain relievers
- Lifestyle modifications, including dietary changes, increased sleep, and stress reduction



Joint and muscle aches

- Over-the-counter nonsteroidal anti-inflammatory drugs to help relieve pain and swelling
- Icing and resting the affected area



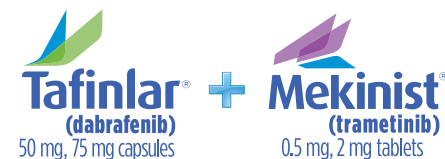
Cough

- Cough drops, expectorants, cough suppressants, or antihistamines
- Taking a hot, steamy shower to loosen mucus
- Using a humidifier

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SOME COMMON SIDE EFFECTS MAY BE MANAGEABLE, APPEAR EARLY, AND DECREASE OVER TIME

Based on clinical trial information, most of the side effects* associated with TAFINLAR + MEKINIST in patients with BRAF+ melanoma occur within 3 months of starting treatment and decrease over 12 months.

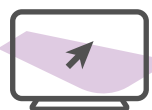
Although your health care provider may advise you to pause or stop treatment with TAFINLAR + MEKINIST due to side effects, additional analysis of the clinical trial data shows that in patients being treated for BRAF+ melanoma after surgery, 90% (97/108) of the side effects that led to stopping treatment were recovered or resolved, and 6% (7/108) of patients were in the process of recovering 30 days after treatment ended.†



Remember that many side effects that lead to discontinuation of TAFINLAR + MEKINIST may resolve with time and appropriate management by you and your health care provider.

*The most common side effects of TAFINLAR + MEKINIST for melanoma that has spread to other parts of the body or cannot be removed by surgery include: fever, rash, nausea, headache, chills, diarrhea, vomiting, high blood pressure (hypertension), joint aches, swelling of the face, arms, or legs and cough.

†Of patients who stopped treatment due to side effects, 26% were taking TAFINLAR + MEKINIST and 3% were taking a placebo. The most common cause of ending treatment with TAFINLAR + MEKINIST was fever (9%).



Watch videos with more tips for managing common side effects of TAFINLAR + MEKINIST at www.us.TafinlarMekinist.com

IMPORTANT SAFETY INFORMATION

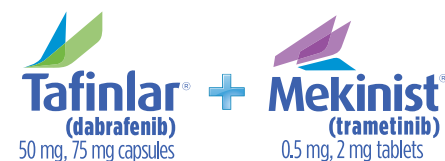
What is the most important information I should know about TAFINLAR in combination with MEKINIST? TAFINLAR and MEKINIST may cause serious side effects, including:

Risk of new skin cancers. TAFINLAR, when used in combination with MEKINIST, may cause a type of skin cancer called cutaneous squamous cell carcinoma, keratoacanthoma, basal cell carcinoma, or melanoma. Talk with your health care provider about your risk for these cancers.

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BE READY FOR THE POSSIBILITY OF FEVER

Fever is the most common side effect of treatment with TAFINLAR + MEKINIST. Roughly half of people taking TAFINLAR + MEKINIST will experience fever in the first month of treatment.

What to do if you think you have a fever

As soon as you start feeling unusually warm or cold, check your temperature. Although increased body temperature is the clearest sign of a fever, there are others, including:

If your thermometer reads 100.4 °F or higher, or if you experience any of these symptoms, stay hydrated and call your health care provider.



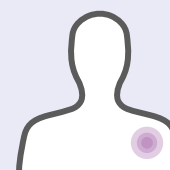
Headache



Tiredness



Chills or shaking chills



Body aches



Sudden confusion or forgetfulness

In some cases, chills or shaking chills, dehydration (too much fluid loss), low blood pressure, dizziness, or kidney problems can occur with the fever.



Not all patients who develop fever experience symptoms, so it's important to monitor your temperature regularly and contact your health care provider if a fever develops.

IMPORTANT SAFETY INFORMATION (continued)

Risk of new skin cancers (continued). Check your skin and tell your health care provider right away about any skin changes, including a new wart, skin sore, or reddish bump that bleeds or does not heal, or a change in size or color of a mole.

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TALKING WITH YOUR HEALTH CARE PROVIDER ABOUT FEVER

When you call your health care provider, be sure to mention:

- Your current temperature and what you used to record it (for example, a digital thermometer)
- When your fever began and how long it has been present
- If you have chills, stomach or breathing problems, dizziness, fatigue, and/or difficulty with or less frequent urination
- What fluids you've had to drink, and how much, in the last 24 hours
- If you've been around any sick people or traveled recently



If you have a fever, your health care provider may temporarily pause or permanently stop your treatment with TAFINLAR + MEKINIST. Your health care provider will treat you as needed for your fever and any signs and symptoms of infection, and should check your kidney function during and after you have had severe fever. At your health care provider's discretion, pausing treatment may help lower your fever so you can resume taking TAFINLAR + MEKINIST as prescribed. But do not pause, stop taking, or change your dosage of TAFINLAR + MEKINIST unless your health care provider tells you to do so.



Results from a clinical trial show there is an updated way to manage fever with TAFINLAR + MEKINIST that may reduce the risk of severe fever and fever-related events without affecting the potential benefits of the medication. Talk to your health care provider to learn more.

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Tafinlar[®] + **Mekinist**[®]
 (dabrafenib) (trametinib)
 50 mg, 75 mg capsules 0.5 mg, 2 mg tablets

APPROVED USES

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IMPORTANT SAFETY INFORMATION

What is the most important information I should know about TAFINLAR in combination with MEKINIST? TAFINLAR and MEKINIST may cause serious side effects, including:

Risk of new skin cancers. TAFINLAR, when used in combination with MEKINIST, may cause a type of skin cancer called cutaneous squamous cell carcinoma, keratoacanthoma, basal cell carcinoma, or melanoma. Talk with your health care provider about your risk for these cancers.

Check your skin and tell your health care provider right away about any skin changes, including a new wart, skin sore, or reddish bump that bleeds or does not heal, or a change in size or color of a mole.

Your health care provider should check your skin before you start treatment, and every 2 months while on treatment, to look for any new skin cancers. Your health care provider should continue to check your skin for 6 months after you stop taking TAFINLAR and MEKINIST.

Your health care provider should also check for cancers that may not occur on the skin. Tell your health care provider about any new symptoms that have developed while taking TAFINLAR and MEKINIST in combination.

Bleeding problems. TAFINLAR and MEKINIST in combination can cause serious bleeding problems, especially in your brain or stomach, that can lead to death. Call your health care provider and get medical help right away if you have any signs of bleeding, including:

- headaches, dizziness, or feeling weak
- coughing up blood or blood clots
- vomiting blood or your vomit looks like “coffee grounds”
- red or black stools that look like tar

Inflammation of the intestines or tears (perforation) of the stomach or intestines. MEKINIST, alone or in combination with TAFINLAR, can cause inflammation of your intestines, or tears in the stomach or intestines that can lead to death. Tell your health care provider right away if you have any of the following symptoms:

- bleeding (see “Bleeding problems”)
- diarrhea (loose stools) or more bowel movements than usual
- stomach-area (abdomen) pain or tenderness
- fever
- nausea

Blood clots. TAFINLAR and MEKINIST in combination can cause blood clots in your arms or legs, which can travel to your lungs and lead to death. Get medical help right away if you have the following symptoms:

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IMPORTANT SAFETY INFORMATION (continued)

- chest pain
- sudden shortness of breath or trouble breathing
- pain in your legs with or without swelling
- swelling in your arms or legs
- a cool, pale arm or leg

Heart problems, including heart failure. Your health care provider should check your heart function before you start taking TAFINLAR and MEKINIST in combination, and during treatment. Call your health care 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 and feet
- feeling lightheaded

Eye problems. TAFINLAR and MEKINIST, in combination, can cause severe eye problems that can lead to blindness. Call your health care provider right away if you get these symptoms of eye problems:

- blurred vision, loss of vision, or other vision changes
- seeing color dots
- halo (seeing blurred outline around objects)
- eye pain, swelling, or redness

Lung or breathing problems. TAFINLAR and MEKINIST, in combination, can cause lung or breathing problems. Tell your health care provider if you have any new or worsening symptoms of lung or breathing problems, including:

- shortness of breath
- cough

Fever. Fever is common during treatment with TAFINLAR and MEKINIST, but it may also be serious. When taking TAFINLAR and MEKINIST, in combination, fever may happen often or may be 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 health care provider right away if you get a fever while taking TAFINLAR or MEKINIST.

Your health care provider may temporarily or permanently stop your treatment or change your dose of MEKINIST with TAFINLAR if you have fevers. Your health care provider will treat you as needed for your fever and any signs and symptoms of infection and should check your kidney function during and after you have had severe fever.

Serious skin reactions. Skin rash is a common side effect of TAFINLAR and MEKINIST. In some cases, these rashes and other skin reactions can be severe or serious, may need to be treated in a hospital, or lead to death.

- tell your health care provider if you get a skin rash or acne that bothers you or worsens
- **tell your health care provider right away if you develop any of the following signs or symptoms of a severe skin reaction, including:**
 - blisters or peeling of your skin
 - mouth sores
 - high fever or flu-like symptoms
 - blisters on your lips, or around your mouth or eyes
 - enlarged lymph nodes

Increased blood sugar (hyperglycemia). Some people may develop high blood sugar or worsening diabetes during treatment with TAFINLAR and MEKINIST in combination. If you are diabetic, your health care provider should check your blood sugar levels closely during treatment with TAFINLAR and MEKINIST. Your diabetes medicine may need to be changed. Tell your health care 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

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IMPORTANT SAFETY INFORMATION (continued)

TAFINLAR may cause healthy red blood cells to break down too early in people with glucose-6-phosphate dehydrogenase (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 health care provider if you have any of the following signs or symptoms:

- yellow skin (jaundice)
- weakness or dizziness
- shortness of breath

Hemophagocytic Lymphohistiocytosis (HLH). TAFINLAR when taken with MEKINIST may increase the risk of a type of overactivity of the immune system (hemophagocytic lymphohistiocytosis) that can cause fever, swollen glands, bruising, or skin rash. If you experience a combination of these symptoms, call your health care provider right away.

TAFINLAR and MEKINIST, in combination, can harm your unborn baby.

Your health care provider will do a test to see if you are pregnant before starting treatment with TAFINLAR and MEKINIST in combination.

Women who are able to become pregnant should use effective birth control (contraception) during treatment with TAFINLAR and MEKINIST in combination, and for 4 months after stopping treatment with TAFINLAR and MEKINIST.

Birth control using hormones (such as birth control pills, injections, or transdermal systems) may not work as well while you are taking TAFINLAR and MEKINIST in combination. You should use another effective method of birth control while taking TAFINLAR and MEKINIST in combination.

Talk to your health care provider about birth control methods that may be right for you during this time.

Tell your health care provider right away if you become pregnant, or think you might be pregnant, during treatment with TAFINLAR and MEKINIST in combination.

Men (including those who have had a vasectomy) with a female partner who is able to become pregnant should use condoms during sexual intercourse during treatment with TAFINLAR and MEKINIST for at least 4 months after your last dose of TAFINLAR and MEKINIST in combination.

The most common side effects of TAFINLAR, in combination with MEKINIST, when used in patients with melanoma that has spread to other parts of the body or cannot be removed by surgery include:

- fever
- rash
- nausea
- headache
- chills
- diarrhea
- vomiting
- high blood pressure (hypertension)
- joint aches
- swelling of the face, arms, or legs
- cough

The most common side effects of TAFINLAR, in combination with MEKINIST, when used in patients to help prevent melanoma from coming back after the cancer has been removed by surgery include:

- fever
- tiredness
- nausea
- headache

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IMPORTANT SAFETY INFORMATION (continued)

- rash
- chills
- diarrhea
- vomiting
- joint aches
- muscle aches

New or worsening high blood pressure (hypertension). Your health care provider should check your blood pressure during treatment with MEKINIST. Call your health care provider right away if you develop high blood pressure, your blood pressure worsens, or you have severe headache, lightheadedness, blurry vision, or dizziness.

Fertility problems. TAFINLAR and MEKINIST, in combination, may cause fertility problems in women. This could affect the ability to become pregnant. Talk to your health care provider if this is a concern for you.

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

Nursing mothers. It is not known if TAFINLAR and/or MEKINIST pass into breast milk. Do not breastfeed during treatment, and for 4 months after your last dose of TAFINLAR and MEKINIST. Talk to your health care provider about the best way to feed your baby during this time.

These are not all the possible side effects of TAFINLAR and MEKINIST. For more information about side effects, ask your health care provider or pharmacist.

Before you take TAFINLAR and MEKINIST in combination, tell your health care provider about all your medical conditions, including if you:

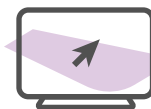
- have had bleeding problems or blood clots
- have stomach problems
- have inflammation of the colon
- have heart problems
- have eye problems
- have lung or breathing problems
- have high blood pressure (hypertension)
- have liver or kidney problems
- have diabetes
- plan to have surgery, dental, or other medical procedures
- have a deficiency of the G6PD enzyme
- are pregnant or plan to become pregnant
- are breastfeeding or plan to breastfeed

Tell your health care 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 health care provider and pharmacist when you get a new medicine.

Please read the Medication Guide for TAFINLAR and the Patient Information for MEKINIST and discuss any questions you have with your health care provider.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see accompanying full Prescribing Information for TAFINLAR, including Medication Guide, and full Prescribing Information for MEKINIST, including Patient Information.



Learn about the potential side effects of TAFINLAR + MEKINIST.

Visit www.us.TafinlarMekinist.com

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KEEP TRACK OF IMPORTANT INFORMATION

Keep track of your side effects and inform your health care provider about any that bother you or do not go away. When you begin TAFINLAR + MEKINIST, keep a list of all your medicines. Whenever you start a new medicine, update the list and share it with your health care provider. **This is important because certain medicines may affect each other, resulting in side effects.**

It's important to let your health care provider know about any side effects that you experience. Keep their contact information readily available and keep this brochure handy for your next appointment.

Name _____ Phone number _____

Email address _____ Website _____

Type of side effect	When did the side effect begin?	Steps taken to manage the side effect (for example, taking a pain reliever)

Name of current medication	What's the dosage?	How often is it taken?

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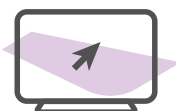


BE READY TO ADVOCATE FOR YOUR HEALTH

Caregivers can help, too! Talk to your caregiver about how they can help you prepare for possible side effects and how to help you manage them if they occur.



Keep this guide handy to track potential side effects and refresh your memory about what to do if you experience them.



Visit www.us.TafinlarMekinist.com to learn more about the No. 1 prescribed targeted therapy for BRAF+ melanoma worldwide

IMPORTANT SAFETY INFORMATION (continued)

Risk of new skin cancers (continued). Your health care provider should check your skin before you start treatment, and every 2 months while on treatment, to look for any new skin cancers. Your health care provider should continue to check your skin for 6 months after you stop taking TAFINLAR and MEKINIST.

Your health care provider should also check for cancers that may not occur on the skin. Tell your health care provider about any new symptoms that have developed while taking TAFINLAR and MEKINIST in combination.

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