





# TIPS FOR STARTING TREATMENT

To help you feel prepared to start treatment with TAFINLAR® (dabrafenib) capsules + MEKINIST® (trametinib) tablets, find answers to some common questions.

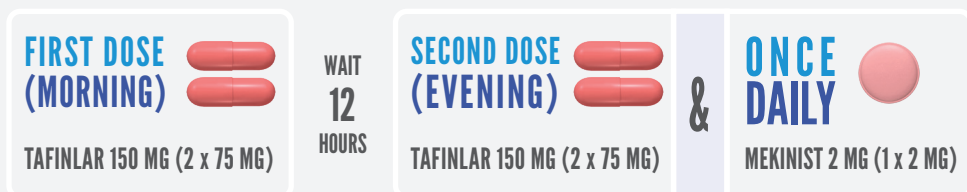
## HOW SHOULD I TAKE TAFINLAR + MEKINIST?

TAFINLAR + MEKINIST is a combination treatment: 2 different medications with 2 different strengths. It's important to take each dose (orally, through the mouth) at the recommended time, at least 1 hour before or at least 2 hours after eating.

 For **TAFINLAR** (the dark pink capsule), you'll be taking 2 capsules twice daily, 12 hours apart. That means 2 capsules in the morning and 2 capsules in the evening. Never open, crush, or break TAFINLAR capsules.

 For **MEKINIST** (the light pink circular tablet), you'll take this pill just once daily at the same time each day. Try taking MEKINIST with either your morning or evening dose of TAFINLAR, so you never miss a dose.

Here's an example of an average dosing schedule for someone taking TAFINLAR + MEKINIST:



Take MEKINIST at the same time each day with either the morning or evening dose of TAFINLAR.

Follow your health care provider's directions when taking your dose. Don't change your dose or stop TAFINLAR + MEKINIST unless your health care provider tells you to.

*Capsules and tablet are not actual size. Keep TAFINLAR, MEKINIST, and all medicines out of the reach of children.*

## WHAT IF I MISS A DOSE?

If you miss a dose of TAFINLAR + MEKINIST, or both, don't panic—it happens. Take your dose as soon as you remember, unless:

- You've missed TAFINLAR and it is within 6 hours of your next scheduled dose
- You've missed MEKINIST and it is within 12 hours of your next scheduled dose

If you find yourself in either of those scenarios, just take your next dose at the regular time. Do not make up for the missed dose.

Please see Important Safety Information, and click [here](#) for full Prescribing Information for TAFINLAR and click [here](#) for full Prescribing Information for MEKINIST.

## HOW SHOULD I STORE TAFINLAR + MEKINIST?

Because they are 2 different medications, TAFINLAR® (dabrafenib) capsules and MEKINIST® (trametinib) tablets require storing in slightly different temperatures. Here are some guidelines to follow:



STORE  
TAFINLAR

AT ROOM TEMPERATURE (68°F-77°F)



STORE  
MEKINIST

IN THE REFRIGERATOR (36°F-46°F)

- Keep MEKINIST dry and away from moisture and light
- The bottle of MEKINIST contains a packet that helps keep your medicine dry. Do not throw away this packet
- Keep MEKINIST in the original bottle. Do not place tablets in a pill box
- Safely throw away MEKINIST that is expired or no longer needed

*Capsules and tablet are not actual size. Keep TAFINLAR, MEKINIST, and all medicines out of the reach of children.*

## WHAT ARE THE POSSIBLE SIDE EFFECTS?

- As with many cancer treatments, there may be [possible side effects](#) of taking TAFINLAR + MEKINIST
- By preparing with your health care team, you can better manage any side effects that may occur
- Tell your health care provider about any side effects you experience. **These are the most common side effects:**



FEVER



HEADACHE



FATIGUE



DIARRHEA



JOINT ACHES



RASH

For more information, please see the [TAFINLAR + MEKINIST Patient Brochure](#).

## HOW CAN I MANAGE PYREXIA (FEVER)?

About half of patients taking TAFINLAR + MEKINIST will experience fever, most commonly during the first month of treatment. These fevers are generally manageable. About 5% of patients will experience severe fever. Refer to our [fever guide](#) for help.

Feeling unusually warm or cold? It might be a fever. Here's what you should do:

- Check your temperature with a thermometer
- Call your health care provider right away if your thermometer reads 100.4°F or higher while taking TAFINLAR + MEKINIST. He or she may recommend that you:
  - » Drink liquids (for example, water, soups, or ice pops)
  - » Get plenty of rest
  - » Place a cold cloth on your forehead if you feel hot
  - » Use over-the-counter fever-reducing medicines
  - » Stop or temporarily pause your treatment of TAFINLAR + MEKINIST, which may help mitigate your fever so you can return to taking TAFINLAR + MEKINIST as prescribed
- If your temperature is higher than 104°F and/or you feel faint or are losing consciousness, tell your health care provider immediately. If he or she advises going to the emergency department, be sure to tell the emergency health care professionals that you are taking TAFINLAR + MEKINIST

**Please see Important Safety Information, and click [here](#) for full Prescribing Information for TAFINLAR and click [here](#) for full Prescribing Information for MEKINIST.**

# IS THERE PATIENT SUPPORT AVAILABLE?

From financial assistance to patient stories, there are a number of helpful programs for eligible patients taking TAFINLAR® (dabrafenib) capsules + MEKINIST® (trametinib) tablets. Explore the following resources:

- Save on copayments through the [Novartis Oncology Universal Co-Pay Program](#)
- Get a free supply of treatment with the Free Trial & Access Program through [Patient Assistance Now Oncology \(PANO\)](#)
- Find support from [advocacy groups and organizations](#)
- Download our brochure and more [helpful materials](#)
- Check out [advice and support for caregivers](#)

## FOR MORE INFORMATION, VISIT OUR [FREQUENTLY ASKED QUESTIONS](#).

### 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, should not be used to treat 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, are right for you.

It is not known if TAFINLAR and MEKINIST, in combination, are safe and effective in children.

### 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
- vomiting blood or your vomit looks like "coffee grounds"
- coughing up blood or blood clots
- red or black stools that look like tar

Please click [here](#) for full Prescribing Information for TAFINLAR and click [here](#) for full Prescribing information for MEKINIST.

## IMPORTANT SAFETY INFORMATION (CONTINUED)

**Inflammation of the intestines or tears (perforation) of the stomach or intestines.** MEKINIST® (trametinib) tablets, alone or in combination with TAFINLAR® (dabrafenib) capsules, can cause inflammation of your intestines, or tears in the stomach or intestines that can lead to death. Tell your health care provider immediately 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:

- 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

**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

Please click [here](#) for full Prescribing Information for TAFINLAR and click [here](#) for full Prescribing information for MEKINIST.

## IMPORTANT SAFETY INFORMATION (CONTINUED)

provider if you have any of the following signs or symptoms:

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

**TAFINLAR® (dabrafenib) capsules and MEKINIST® (trametinib) tablets, in combination, can harm your unborn baby.** 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.

**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
- fatigue
- nausea
- headache
- 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 of 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 of 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
- are a man (including one who has had a vasectomy) with a female partner of reproductive potential
  - » men (including those who have had a vasectomy) should use condoms during sexual intercourse during treatment with TAFINLAR and MEKINIST and for at least 4 months after your last dose of TAFINLAR and MEKINIST

**Please click [here](#) for full Prescribing Information for TAFINLAR and click [here](#) for full Prescribing information for MEKINIST.**

## IMPORTANT SAFETY INFORMATION (CONTINUED)

- 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](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

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

