

How should I take TAFINLAR + MEKINIST?

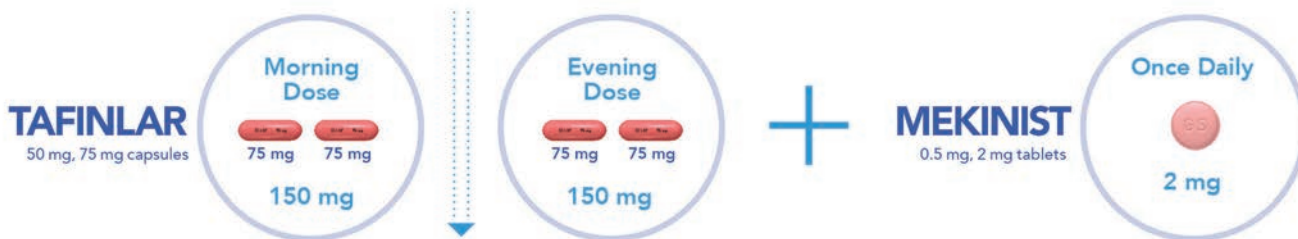
TAFINLAR + MEKINIST is prescription medication used to treat a type of lung cancer called metastatic non-small cell lung cancer (NSCLC) that has a certain type of abnormal "BRAF V600E" gene.

TAFINLAR should not be used to treat people with wild-type BRAF NSCLC

i Recommended dose:
TAFINLAR® (dabrafenib) capsules 150 mg twice daily + MEKINIST® (trametinib) tablets 2 mg once daily by mouth

Take your medication at least 1 hour before or at least 2 hours after eating.

Capsules and tablet shown are not actual size.



12-hour interval between TAFINLAR doses

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

- ◆ Take TAFINLAR + MEKINIST exactly as your health care provider tells you. Do not change your dose or stop TAFINLAR + MEKINIST unless your health care provider tells you
- ◆ Take TAFINLAR 2 times a day, about 12 hours apart and MEKINIST one time a day, at the same time each day
- ◆ Take TAFINLAR and MEKINIST 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
- ◆ If you miss a dose of MEKINIST, take it as soon as you remember. If it is less than 12 hours before your next scheduled dose, skip the missed dose. Just take the next dose at your regular time

It is important that you understand and follow your health care provider's directions for taking TAFINLAR + MEKINIST. Your health care provider may change your dose or stop treatment temporarily if you have side effects. Do not change your dose, or stop TAFINLAR or MEKINIST, unless your health care provider tells you to.

IMPORTANT SAFETY INFORMATION

TAFINLAR and MEKINIST, in combination, may cause serious side effects, including: risk of new cancers, bleeding problems, inflammation of the intestines or tears (perforation) of the stomach or intestines, blood clots, heart problems, including heart failure, eye problems, lung or breathing problems, fever, serious skin reactions, increased blood sugar (hyperglycemia), and may cause healthy red blood cells to break down too early in people with glucose-6-phosphate dehydrogenase (G6PD) deficiency.

Please see additional Important Safety Information on [pages 6-8](#), and [click here](#) for full Prescribing Information for TAFINLAR, including Medication Guide, and [click here](#) for full Prescribing Information for MEKINIST, including Patient Information.



Keep track of your daily doses of TAFINLAR + MEKINIST

- ◆ TAFINLAR® (dabrafenib) capsules 150 mg twice a day: Check the box when you take each dose, and note the time the dose was taken (AM and PM)
- ◆ MEKINIST® (trametinib) tablets 2 mg once a day: Check the box when you take your dose, and note the time the dose was taken (AM or PM—circle one)
- ◆ Tell your health care provider if you have any side effect that bothers you or that does not go away

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- ◆ Store TAFINLAR at room temperature, between 68°F to 77°F (20°C - 25°C)
- ◆ Store MEKINIST in the refrigerator, between 36°F to 46°F (2°C - 8°C).
- ◆ Keep MEKINIST dry and away from moisture and light
- ◆ The bottle of MEKINIST contains a desiccant packet to help keep your medicine dry. Do not throw away the desiccant packet
- ◆ Keep MEKINIST in its original bottle. Do not place tablets in a pill box

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- ◆ Safely throw away MEKINIST that is out of date or no longer needed

Keep TAFINLAR, MEKINIST, and all medicines out of the reach of children.

Please see Important Safety Information on [pages 6-8](#), and [click here](#) for full Prescribing Information for TAFINLAR, including Medication Guide, and [click here](#) for full Prescribing Information for MEKINIST, including Patient Information.



Keep track of your daily doses of TAFINLAR + MEKINIST

- ◆ TAFINLAR® (dabrafenib) capsules 150 mg twice a day: Check the box when you take each dose, and note the time the dose was taken (AM and PM)
- ◆ MEKINIST® (trametinib) tablets 2 mg once a day: Check the box when you take your dose, and note the time the dose was taken (AM or PM—circle one)
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- ◆ Keep MEKINIST dry and away from moisture and light
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APPROVED USE

TAFINLAR® (dabrafenib) capsules, in combination with MEKINIST® (trametinib) tablets, is a prescription medication used to treat a type of lung cancer called non-small cell lung cancer (NSCLC) that has spread to other parts of the body (metastatic NSCLC), and that has a certain type of abnormal “*BRAF V600E*” gene.

TAFINLAR, in combination with MEKINIST, should not be used to treat people with a type of lung cancer called wild-type *BRAF* NSCLC.

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 the risk of new cancers: TAFINLAR, when used in combination with MEKINIST, may cause a type of skin cancer called cutaneous squamous cell carcinoma (cuSCC), 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.

TAFINLAR and MEKINIST in combination may cause serious side effects, including:

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 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

IMPORTANT SAFETY INFORMATION (continued)

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.

Serious skin reactions. Rash and other skin reactions are a common side effect of TAFINLAR and MEKINIST in combination. In some cases these rashes and other skin reactions can be severe or serious, and may need to be treated in a hospital. Call your health care 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 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 provider if you have any of the following signs or symptoms:

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

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

TAFINLAR and MEKINIST, 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 people with NSCLC, include:

- fever
- fatigue
- nausea
- vomiting
- diarrhea
- dry skin
- decreased appetite
- rash
- swelling of the face, arms, and legs
- chills
- bleeding
- cough
- shortness of breath

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.



IMPORTANT SAFETY INFORMATION (continued)

Fertility problems. TAFINLAR® (dabrafenib) capsules and MEKINIST® (trametinib) tablets, 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 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 [click here](#) for full Prescribing Information for TAFINLAR, including Medication Guide, and [click here](#) for full Prescribing Information for MEKINIST, including Patient Information.



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