

UPDATED


Tafinlar[®]
(dabrafenib)
50 mg, 75 mg capsules




Mekinist[®]
(trametinib)
0,5 mg, 2 mg tablets

PREPARING FOR TREATMENT WITH TAFINLAR + MEKINIST

TIPS FOR MANAGING FEVER

For patients on treatments for cancer, side effects are often a reality. Treatment with TAFINLAR + MEKINIST can also cause side effects, some severe, so we want you to be prepared for the most common side effect: fever.

It's important to let your health care team know about any side effect, including fever, that you experience.

Keep their office number stored in your phone.

My Oncologist

Name _____

Phone _____

APPROVED USE

TAFINLAR and MEKINIST are prescription medicines that can be used in combination 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, is not for use in treating people with wild-type *BRAF* NSCLC.

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.

IMPORTANT SAFETY INFORMATION

TAFINLAR and MEKINIST in combination may cause serious side effects, including risk of new skin 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, and increased blood sugar (hyperglycemia). TAFINLAR may cause healthy red blood cells to break down too early in people with glucose-6-phosphate dehydrogenase (G6PD) deficiency. TAFINLAR and MEKINIST, in combination, may increase the risk of hemophagocytic lymphohistiocytosis (HLH) and can harm your unborn baby.

Please see Important Safety Information throughout this brochure and the Summary of Important Information on pages 8 to 11.

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

EXPECTING FEVER

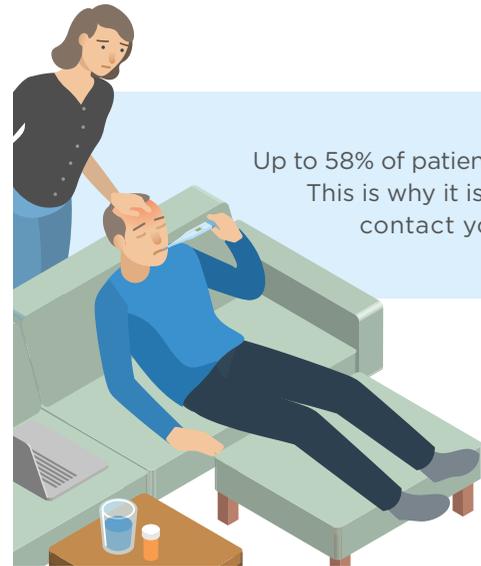
SEE IMPORTANT SAFETY INFORMATION BELOW AND THROUGHOUT THIS BROCHURE.

Fever is a common side effect in more than half of patients

These fevers may be caused by a biological response to TAFINLAR + MEKINIST, and may not be from any kind of infection.

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 and MEKINIST.**

About 5% of patients will experience severe fever. Roughly half of the patients who experience pyrexia do so in about the first four weeks of treatment.



Up to 58% of patients on TAFINLAR + MEKINIST experienced a fever. This is why it is important to check your temperature and contact your health care provider if you do have a fever.

IMPORTANT SAFETY INFORMATION

TAFINLAR and MEKINIST in combination may cause serious side effects, including risk of new skin 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, and increased blood sugar (hyperglycemia). TAFINLAR may cause healthy red blood cells to break down too early in people with glucose-6-phosphate dehydrogenase (G6PD) deficiency. TAFINLAR and MEKINIST, in combination, may increase the risk of hemophagocytic lymphohistiocytosis (HLH) and can harm your unborn baby.

EXPERIENCING FEVER

Be ready to take action



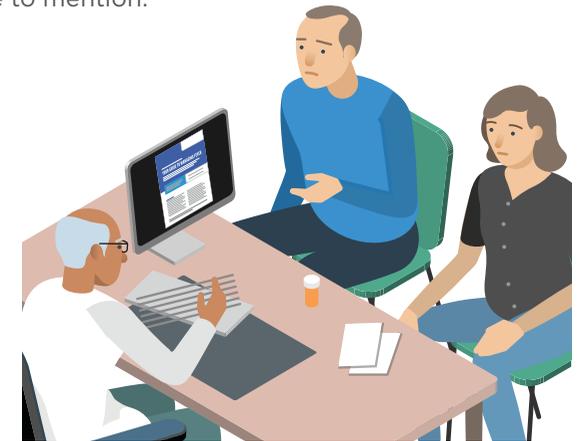
As soon as you start feeling unusually warm or cold, check your temperature. If your thermometer reads 100.4°F or higher, contact your health care provider. They may tell you to permanently stop or temporarily pause your treatment with TAFINLAR + MEKINIST at their discretion. A temporary pause in your treatment may help to mitigate your fever so you can return to taking TAFINLAR + MEKINIST as prescribed.

And although increased body temperature is the clearest sign of a fever, there are others: **headache, fatigue, chills, body aches, and sudden confusion or forgetfulness.** In some cases it may feel like you have influenza. If you experience any of these symptoms, make sure to stay hydrated.

Talking with your health care team about fever

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

- ✓ Your current temperature, and what you used to record it (eg, 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 difficult or less frequent urinating
- ✓ What fluids you've had to drink, and how much, in the last 24 hours
- ✓ If you've been around any sick people, or if you've traveled recently



Please see additional Important Safety Information throughout this brochure and the Summary of Important Information on pages 8 to 11.

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



STRATEGIES FOR MANAGING FEVER

At-home fever management

You may be able to manage your fever at home. Your health care provider may recommend that you:



Place a cold cloth on your forehead if you feel hot



Use over-the-counter antifever medications



Get plenty of rest



Drink liquids (for example, water, soups, ice pops) to prevent dehydration



Supporters—you can help, too

Help your loved one take and record his or her temperature every 2 to 3 hours. You can also help encourage your loved one to drink enough fluids and get enough rest.

Dosing and fevers

If you have a fever, talk to your health care provider. Your health care provider may permanently stop or temporarily pause your treatment with TAFINLAR + MEKINIST. At your health care provider's discretion, pausing treatment may help mitigate your fever so you can return to 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.

Remember to keep track of your side effects and inform your health care provider about any side effect that bothers you or that does not go away.

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:

- 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

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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.

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 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)

IMPORTANT SAFETY INFORMATION (continued)

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 people with NSCLC, include:

- fever
- tiredness
- 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.

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 additional Important Safety Information throughout this brochure and the Summary of Important Information on pages 8 to 11.

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



SUMMARY OF IMPORTANT INFORMATION FOR TAFINLAR AND MEKINIST

What are TAFINLAR and MEKINIST?

TAFINLAR and MEKINIST are prescription medicines that can be used in combination 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, is not for use in treating people with 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, 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.

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 to 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 mole that changes size or color.

Your health care provider should check your skin before treatment with TAFINLAR and MEKINIST, every 2 months during treatment and for up to 6 months after you stop taking TAFINLAR and MEKINIST to look for any new skin cancers. 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 develop during treatment with TAFINLAR and MEKINIST.

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:

- 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

SUMMARY OF IMPORTANT INFORMATION FOR TAFINLAR AND MEKINIST (continued)

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 such as shortness of breath or 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**

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

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 symptoms of severe high blood sugar such as increased thirst, urinating more often than normal, or urinating an increased amount of urine.

Glucose-6-phosphate dehydrogenase (G6PD) deficiency. 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 health care provider if you have any of the signs or symptoms such as yellow skin (jaundice), weakness or dizziness, or 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.



SUMMARY OF IMPORTANT INFORMATION FOR TAFINLAR AND MEKINIST (continued)

What should I tell my health care provider before taking TAFINLAR and MEKINIST?

Before you take TAFINLAR, in combination with MEKINIST, 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
- have a deficiency of the G6PD enzyme
- plan to have surgery, dental, or other medical procedures
- are pregnant or plan to become pregnant
 - 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
 - men (including one who has had a vasectomy) with a female partner of reproductive potential

should use condoms during sexual intercourse during treatment with TAFINLAR and MEKINIST and for at least 4 months after the last dose of TAFINLAR and MEKINIST

- TAFINLAR and MEKINIST in combination may cause fertility problems in women. This could affect the ability to become pregnant
- 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
- are breastfeeding or planning to breastfeed
 - it is not known if TAFINLAR and/or MEKINIST passes 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

What other medications might interact with TAFINLAR and MEKINIST?

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.

What laboratory tests or monitoring do I need if I am prescribed TAFINLAR and MEKINIST?

Your health care provider should check your skin, heart function, eyes, and blood sugar (if you are diabetic). Your health care provider may eventually stop checking some of these tests. Your health care provider should conduct a pregnancy test before you start TAFINLAR and MEKINIST if you are capable of having children.

SUMMARY OF IMPORTANT INFORMATION FOR TAFINLAR AND MEKINIST (continued)

What are other side effects of TAFINLAR and MEKINIST in combination?

The most common side effects of TAFINLAR, in combination with MEKINIST, when used in people with NSCLC, include:

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

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General information about the safe and effective use of TAFINLAR and MEKINIST

Do not use TAFINLAR and MEKINIST for a condition for which it was not prescribed. Do not give TAFINLAR and MEKINIST to other people, even if they have the same symptoms that you have. It may harm them. You can ask your health care provider or pharmacist for information about TAFINLAR and MEKINIST that is written for health care professionals.

These are not all the possible side effects of TAFINLAR and MEKINIST. For more information, talk with your health care provider or pharmacist or call 1-888-669-6682. The FDA-approved product labeling or prescribing information can be found at www.us.tafinlarmekinist.com.

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.

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Go to the emergency department **immediately** if **your temperature is higher than 104°F** and/or **you feel faint or are losing consciousness**. Make sure to tell the emergency department health care professionals that you are taking TAFINLAR + MEKINIST.

