TAFINLAR + MEKINIST

Patient Information for a type of lung cancer called metastatic non-small cell lung cancer (NSCLC) with a BRAF V600E gene.

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.

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

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

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® (dabrafenib) 50 mg, 75 mg capsules + Mekinist® (trametinib) 0.5 mg, 2 mg tablets

WELCOME

This patient information is meant to help you and your loved ones understand TAFINLAR® (dabrafenib) taken with MEKINIST® (trametinib) to treat a kind of lung cancer called metastatic NSCLC with an abnormal BRAF V600E gene.

Read this patient information before you start taking TAFINLAR with MEKINIST and each time you get a refill.

This information does not take the place of talking to your doctor about your condition or treatment.

TABLE OF CONTENTS

About TAFINLAR

4 What is the most important information I should know about TAFINLAR?
6 What is TAFINLAR?
7 What should I tell my health care provider before taking TAFINLAR?
10 How should I take TAFINLAR?
11 What are the possible side effects of TAFINLAR?
16 How should I store TAFINLAR?
16 General information about the safe and effective use of TAFINLAR
17 What are the ingredients in TAFINLAR?

About MEKINIST

18 What is the most important information I should know about MEKINIST?
20 What is MEKINIST?
20 What should I tell my health care provider before taking MEKINIST?
23 How should I take MEKINIST?
24 What are the possible side effects of MEKINIST?
29 How should I store MEKINIST?
30 General information about the safe and effective use of MEKINIST
31 What are the ingredients in MEKINIST?

Patient Support

32 Co-pay Assistance Program
33 Patient Assistance Now Oncology

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® (dabrafenib) 50 mg, 75 mg capsules + Mekinist® (trametinib) 0.5 mg, 2 mg tablets

If your health care provider prescribes TAFINLAR for you to be taken with trametinib, also read the Patient Information leaflet that comes with trametinib.

WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT TAFINLAR?

TAFINLAR may cause serious side effects, including the risk of new cancers:

TAFINLAR, when used alone or with trametinib, may cause a type of skin cancer, called cutaneous squamous cell carcinoma (cuSCC). New melanoma lesions may happen in people who take TAFINLAR alone or with trametinib.

TAFINLAR with trametinib, may cause new cancers including basal cell carcinoma.

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
- change in size or color of a mole

Your health care provider should check your skin before treatment with TAFINLAR, every two months during treatment with TAFINLAR, and for up to 6 months after you stop taking TAFINLAR 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.

See "What are the possible side effects of TAFINLAR?" for more information about side effects.

WHAT IS TAFINLAR?

TAFINLAR is a prescription medicine used with a medicine called trametinib to treat people with 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" gene.

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

It is not known if TAFINLAR alone or TAFINLAR with trametinib is safe and effective in children.

WHAT SHOULD I TELL MY HEALTH CARE PROVIDER BEFORE TAKING TAFINLAR?

Before you take TAFINLAR, tell your health care provider if you:

- have had bleeding problems
- have heart problems
- have eye problems
- 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 effective birth control (contraception) during treatment with TAFINLAR, and for 2 weeks after the last dose of TAFINLAR alone, or for 4 months after the last dose when taking TAFINLAR with trametinib

  - Birth control methods that contain hormones (such as birth control pills, injections, or patches) may not work as well during treatment with TAFINLAR alone or TAFINLAR and trametinib. You should use another effective method of birth control during treatment with TAFINLAR alone or TAFINLAR and trametinib
  - 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 alone or TAFINLAR and trametinib
- are breastfeeding or plan to breastfeed. It is not known if TAFINLAR passes into your breast milk
  - Do not breastfeed during treatment and for 2 weeks after your last dose of TAFINLAR alone, **or** for 4 months after your last dose of TAFINLAR with trametinib. Talk to your health care provider about the best way to feed your baby during this time

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

HOW SHOULD I TAKE TAFINLAR?

- Take TAFINLAR exactly as your health care provider tells you. Do not change your dose or stop TAFINLAR unless your health care 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 of TAFINLAR, 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.

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?"**
- TAFINLAR, when taken with trametinib, can cause serious bleeding problems, especially in your brain or stomach, and 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
  - cough up blood or blood clots
  - vomit blood or your vomit looks like "coffee grounds"
  - red or black stool that looks like tar
- **heart problems**, including heart failure. Your health care provider should check your heart function before and during treatment with TAFINLAR. 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 or feet
  - feeling lightheaded

- **eye problems.** TAFINLAR, when taken alone or with trametinib, 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
  - see color dots
  - halo (see blurred outline around objects)
  - eye pain, swelling, or redness
- **fever.** Fever is common during treatment with TAFINLAR alone or with trametinib, but may also be serious. When taking TAFINLAR with trametinib, fever may happen more often or may be more 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 during treatment with TAFINLAR
- **serious skin reactions.** Rash is a common side effect of TAFINLAR when taken alone, or with trametinib. TAFINLAR, when taken alone or with trametinib, can also cause other skin reactions. 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, alone or with trametinib. If you are diabetic, your health care provider should check your blood sugar levels closely during treatment with TAFINLAR alone or with trametinib. 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 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

The most common side effects of TAFINLAR when taken with trametinib in people with NSCLC include:

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

TAFINLAR may cause fertility problems in females. This could affect your ability to become pregnant. Talk to your health care provider if this is a concern for you.

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

Tell your health care 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 health care 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 Novartis Pharmaceuticals Corporation at 1-888-669-6682.

HOW SHOULD I STORE TAFINLAR?

Store TAFINLAR at room temperature, between 68°F to 77°F (20°C to 25°C).

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

GENERAL INFORMATION ABOUT THE SAFE AND EFFECTIVE USE OF 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. You can ask your health care provider or pharmacist for information about TAFINLAR that is written for health professionals.

WHAT ARE THE INGREDIENTS IN TAFINLAR?

Active ingredient:

dabrafenib

Inactive ingredients:

colloidal silicon dioxide, magnesium stearate, microcrystalline cellulose

Capsule shells:

hypromellose, red iron oxide (E172), titanium dioxide (E171).

If your health care provider prescribes MEKINIST for you to be taken with dabrafenib, also read the Medication Guide that comes with dabrafenib.

WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT MEKINIST?

MEKINIST, when used with dabrafenib, may cause:

- a type of skin cancer, called cutaneous squamous cell carcinoma (cuSCC)
- new cancers including basal cell carcinoma

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
- change in size or color of a mole

Your health care provider should check your skin before treatment with MEKINIST and dabrafenib, every 2 months during treatment with MEKINIST and dabrafenib and for up to 6 months after you stop taking MEKINIST and dabrafenib 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 MEKINIST with dabrafenib.

See "What are the possible side effects of MEKINIST?" for more information about side effects.

WHAT IS MEKINIST?

MEKINIST is a prescription medicine used:

- in combination with dabrafenib 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

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

It is not known if MEKINIST alone or MEKINIST with dabrafenib is safe and effective in children.

WHAT SHOULD I TELL MY HEALTH CARE PROVIDER BEFORE TAKING MEKINIST?

Before you take MEKINIST, tell your health care provider 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 any other medical conditions
- are pregnant or plan to become pregnant. MEKINIST can harm your unborn baby
  - Females who are able to become pregnant should use effective birth control (contraception) during treatment with MEKINIST and for 4 months after your last dose of MEKINIST
  - 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 MEKINIST
- are breastfeeding or plan to breastfeed. It is not known if MEKINIST passes into your breast milk
  - Do not breastfeed during treatment and for 4 months after your last dose of MEKINIST. Talk to your health care provider about the best way to feed your baby during this time

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.

HOW SHOULD I TAKE MEKINIST?

- Take MEKINIST exactly as your health care provider tells you to take it. Do not change your dose or stop MEKINIST unless your health care provider tells you
- Take MEKINIST one time a day, at the same time each day
- Take MEKINIST at least 1 hour before or 2 hours after a meal
- If you miss a dose, 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

WHAT ARE THE POSSIBLE SIDE EFFECTS OF MEKINIST?

MEKINIST may cause serious side effects, including:

- **See "What is the most important information I should know about MEKINIST?"**
- **bleeding problems**. MEKINIST can cause serious bleeding problems, especially in your brain or stomach, and 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
  - cough up blood or blood clots
  - vomit 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 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**" above
  - diarrhea (loose stools) or more bowel movements than usual
  - stomach-area (abdomen) pain or tenderness
  - fever
  - nausea
- **blood clots.** MEKINIST can cause blood clots in your arms or legs, which can travel to your lungs and can 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 and during treatment with MEKINIST. 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.** MEKINIST can cause severe eye problems that might 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

- see color dots
- halo (seeing blurred outline around objects)
- eye pain, swelling, or redness

- **lung or breathing problems.** MEKINIST 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 MEKINIST and dabrafenib, but it may also be serious. When taking MEKINIST with dabrafenib, fever may happen more often or may be more 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 during treatment with MEKINIST
- **serious skin reactions.** Rash is a common side effect of MEKINIST. MEKINIST can also cause other skin reactions. 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 MEKINIST and dabrafenib. If you are diabetic, your health care provider should check your blood sugar levels closely during treatment with MEKINIST and dabrafenib. 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

Common side effects of MEKINIST when taken with dabrafenib in people with NSCLC include:

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

MEKINIST can cause 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, or dizziness.

MEKINIST may cause fertility problems in females. This could affect your ability to become pregnant. Talk to your health care provider if this is a concern for you.

Tell your health care provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of MEKINIST. For more information, ask your health care 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 Novartis Pharmaceuticals Corporation at 1-888-669-6682.

HOW SHOULD I STORE MEKINIST?

- Store MEKINIST in the refrigerator between 36°F to 46°F (2°C to 8°C). Do not freeze
- 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
- Safely throw away MEKINIST that is out of date or no longer needed

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

GENERAL INFORMATION ABOUT THE SAFE AND EFFECTIVE USE OF MEKINIST.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use MEKINIST for a condition for which it was not prescribed. Do not give 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 MEKINIST that is written for health professionals.

For more information, go to **www.MEKINIST.com** or call 1-888-669-6682.

WHAT ARE THE INGREDIENTS IN MEKINIST?

Active ingredient:

trametinib

Inactive ingredients:

Tablet Core: colloidal silicon dioxide, croscarmellose sodium, hypromellose, magnesium stearate (vegetable source), mannitol, microcrystalline cellulose, sodium lauryl sulfate.

Tablet Coating: hypromellose, iron oxide red (2 mg tablets), iron oxide yellow (0.5 mg tablets), polyethylene glycol, polysorbate 80 (2 mg tablets), titanium dioxide.

CO-PAY ASSISTANCE PROGRAM

Novartis Oncology offers access to information about financial assistance for almost all Novartis Oncology products. You may be eligible for immediate co-pay savings on your next prescription:

- Commercially insured patients pay $10 per month per TAFINLAR and MEKINIST or $20 per month for both TAFINLAR and MEKINIST
- Novartis will pay the remaining co-pay, up to $15,000 per calendar year

Limitations apply. Offer is not valid under Medicare, Medicaid, or any other federal or state program. Novartis reserves the right to rescind, revoke, or amend this program without notice. For full terms and conditions, visit **www.CoPay.NovartisOncology.com** or call **1-877-577-7756**.

See if you are eligible at **www.CoPay.NovartisOncology.com**, or call **1-877-577-7756**.

Please click here for full Prescribing Information for TAFINLAR, including Medication Guide, and click here for full Prescribing Information for MEKINIST, including Patient Information.

Patient Assistance Now Oncology

Patient Assistance Now Oncology
Assistance. Access. Answers.

Novartis Oncology is committed to helping you get the medicines you need. Getting access to medications can sometimes be difficult or confusing. Patient Assistance Now Oncology (PANO) offers tools and support designed specifically to help make that process easier.

Support for patients includes:

- Help you understand your insurance coverage and financial responsibilities through the insurance verification process
- Help you identify/determine pharmacies covered by your plan
- Provide insurance and Medicare education
- Provide information about financial assistance that may be available
- Patient Support Counselors who are able to provide information in over 160 languages
- One single point of contact to help guide you through getting access to the medicine prescribed by your doctor

To learn more, call **1-800-282-7630**.

FREE 30-DAY TRIAL

With Patient Assistance Now Oncology (PANO), you can receive a one-time, per patient, per dose free supply of TAFINLAR and MEKINIST for a US Food and Drug Administration (FDA)-approved indication. The supply can be shipped directly to your home or another convenient location, so you can start treatment immediately.

NOTES

NOTES

NOVARTIS

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

Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080 6/17 TML-1147569