

**Patient Information**  
MEKINIST® (MEK-in-ist)  
(trametinib)  
Tablets

If your healthcare 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 healthcare provider about your risk for these cancers.

Check your skin and tell your healthcare 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 healthcare provider should check your skin before treatment with MEKINIST and dabrafenib, every two 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 healthcare provider should also check for cancers that may not occur on the skin. Tell your healthcare 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:

- alone or in combination with a medicine called dabrafenib to treat people with a type of skin cancer called melanoma:
  - that has spread to other parts of the body or cannot be removed by surgery, **and**
  - that has a certain type of abnormal "BRAF" gene.

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.

- 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 healthcare 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 healthcare provider before taking MEKINIST?**

Before you take MEKINIST, tell your healthcare 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 healthcare provider about birth control methods that may be right for you during this time.
- Tell your healthcare 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 healthcare provider about the best way to feed your baby during this time.

**Tell your healthcare 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 healthcare provider and pharmacist when you get a new medicine.

#### **How should I take MEKINIST?**

- Take MEKINIST exactly as your healthcare provider tells you to take it. Do not change your dose or stop MEKINIST unless your healthcare 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 healthcare 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 healthcare 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 healthcare provider should check your heart function before and during treatment with MEKINIST. Call your healthcare 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 healthcare 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 healthcare 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 healthcare 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 healthcare 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 healthcare provider should check your blood sugar levels closely during treatment with MEKINIST and dabrafenib. Your diabetes medicine may need to be changed. Tell your healthcare 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

**The most common side effects of MEKINIST when taken alone include:**

- diarrhea. Call your healthcare provider if you get severe diarrhea.
- swelling of the face, arms, or legs

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

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

**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 healthcare provider should check your blood pressure during treatment with MEKINIST. Call your healthcare 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 healthcare provider if this is a concern for you.

Tell your healthcare 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 healthcare 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 healthcare provider or pharmacist for information about MEKINIST that is written for health professionals.

For more information, go to [www.MEKINIST.com](http://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.

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