

Trametinib (Mekinist)

About This Medicine

TRAMETINIB (tra ME ti nib) treats some types of cancer. It works by blocking a protein that causes cancer cells to grow and multiply. This helps to slow or stop the spread of cancer cells. It is given orally (by mouth).

This medicine may be used for other purposes; ask your care team you have questions.

Possible Side Effects

- Diarrhea (loose bowel movements)
- Swelling that usually affects arms or legs but can affect any part of the body
- Rash

Note: Each of the side effects above was reported in 20% or greater of people treated with trametinib. All possible side effects are not included. Your side effects may be different depending on your cancer diagnosis, condition, or if you are receiving other medicines in combination. Please discuss any concerns or questions with your care team.

Warnings and Precautions

- This medicine may raise your risk of getting a second cancer when given in combination with dabrafenib. It may raise the risk of skin lesions that may or may not be cancer.
- Serious abnormal bleeding, which can be life-threatening when given in combination with dabrafenib. Symptoms may be coughing up blood, throwing up blood (may look like coffee grounds), red or black tarry bowel movements, abnormally heavy menstrual flow, nosebleeds, or any other unusual bleeding. When trametinib is given in combination with dabrafenib, these events may be more severe or life-threatening.
- Serious changes to your eyes such as retinal detachment (the thin membrane that covers the back of the eye separates from the eyeball) and blockage of the small veins in the retina. This can rarely cause blindness.
- Colitis – inflammation (swelling) in the colon, and/or perforation (an abnormal hole) of your esophagus, stomach, or intestine may occur, which can be life-threatening. Symptoms are diarrhea, stomach cramping, and sometimes blood in the bowel movements.
- Inflammation and/or scarring of the lungs. You may have a cough and/or trouble breathing.

- Severe allergic skin reactions, which may be life-threatening. You may develop blisters on your skin that are filled with fluid or a severe red rash all over your body that may be painful. Sometimes, a serious and life-threatening reaction to this medicine can happen that can cause a skin rash, along with problems with your organs, swollen lymph nodes, fever and higher than normal white blood cells.
- Changes in your heart function such as high blood pressure and congestive heart failure - your heart is not pumping blood as well as it should be, and fluid can build up in your body.
- Serious fever reactions when given in combination with dabrafenib. This may be accompanied by dehydration (lack of water in the body from losing too much fluid), low blood pressure and changes in your kidney function which can cause kidney failure.
- Blood clots when given in combination with dabrafenib.. A blood clot in your leg may cause your leg to swell, appear red and warm, and/or cause pain. A blood clot in your lungs may cause trouble breathing, pain when breathing, and/or chest pain.
- Blood sugar levels may change when given in combination with dabrafenib.
- Risk of hemophagocytic lymphohistiocytosis when this medicine is given in combination with dabrafenib. Hemophagocytic lymphohistiocytosis is an immune reaction that can cause damage to blood cells in your bone marrow and any organs in your body, which can be life-threatening.

Note: Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your care team.

How to Take Your Medication

- Take this medicine by mouth without food, at least 1 hour before you eat or 2 hours after you eat, at the same time each day, approximately 24 hours apart. Do not crush or break tablets.
- **Oral solution:** Refer to the medication guide that comes with your medicine for instructions on how to prepare and dose the medicine correctly.
- **Missed dose:** If you miss a dose, you can take it if your next dose is due in more than 12 hours. If your next dose is due in less than 12 hours, then skip the missed dose and take your next dose at the regular time. Do not take 2 doses at the same time or extra doses, instead, continue with your regular dosing schedule.
- If you vomit a dose, take your next dose at the regular time.
- **Overdosage:** If you think you have taken too much of this medicine contact a poison control center or emergency room at once.
- **Handling:** Wash your hands with soap and water, before and after handling your medicine. Your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- This medicine may be present in the urine, stool and other body fluids such as blood, vomit, semen, and vaginal fluids. Take precautions to prevent others from coming in contact with your medicine or your body fluids. Follow safety precautions during your treatment and for as long as directed by your care team after your treatment. If you take a pill each day, follow these precautions every day.
- **Storage: Tablets:** Store this medicine in the refrigerator between 36°F to 46°F (2°C to 8°C). Store in the original container, and do not remove desiccant. Do not place tablets in a pill box. Protect from moisture and light. Keep out of the reach of children and pets.
- **Storage: Oral Solution:** Store in the original container at room temperature, below 77°F (25°C). Do not freeze. Protect from moisture and light. Throw away any unused medicine 35 days after reconstitution. Keep out of the reach of children and pets.



- **Disposal of unused medicine:** Do not flush any expired and/or unused medicine down the toilet or drain unless you are specifically instructed to do so on the medication label. Some facilities have take-back programs and/or other options. If you do not have a take-back program in your area, then please discuss with your care team how to dispose of unused medicine.

Treating Side Effects

- If you throw up or have diarrhea, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).
- Drink enough fluids to keep your urine pale yellow.
- If you have diarrhea, eat low-fiber foods that are high in protein and calories and avoid foods that can irritate your digestive tracts or lead to cramping.
- Ask your care team about medicine that can lessen or stop your diarrhea.
- If you have diabetes, keep good control of your blood sugar level. Tell your care team if your glucose levels are higher or lower than normal.
- If you get a rash do not put anything on it unless your care team says you may. Keep the area around the rash clean and dry. Ask your care team for medicine if your rash bothers you.

Food and Medicine Interactions

- There are no known interactions of trametinib with food. This medication should be taken on an empty stomach.
- This medicine may interact with other medicines. Tell your care team about all the prescription and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs, and others) that you are taking at this time. Also, check with your care team before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.

When to Call Your Care Team

Call your care team if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.4° F (38° C) or higher
- Chills
- Blurred vision or other changes in eyesight such as loss of vision
- Flashes of light and/or dark areas in your field of vision, colored dots, or halos
- Eye pain, swelling, or redness
- Headache that does not go away
- Feeling dizzy or lightheaded
- Feeling that your heart is beating in a fast or not normal way (palpitations)
- Pain in your chest
- Dry cough
- Wheezing and/or trouble breathing
- Swollen lymph nodes in your neck and/or armpits



- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicine
- Throwing up more than 3 times a day
- Trouble swallowing
- Severe pain in your abdomen that does not go away
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
- Signs of abnormal bleeding such as coughing up blood, throwing up blood (may look like coffee grounds), easy bleeding or bruising, red or black tarry bowel movements, abnormally heavy menstrual flow, nosebleeds, or any other unusual bleeding
- Swelling of your legs, feet, ankles, arms, and/or face
- Your leg is swollen, red, warm, and/or painful
- Weight gain of 5 pounds in one week (fluid retention)
- Decreased or very dark urine
- Flu-like symptoms: fever, headache, muscle and joint aches, and tiredness
- A new rash and/or itching or a rash that is not relieved by prescribed medicines
- New skin lesions
- Abnormal blood sugar
- Unusual thirst, passing urine often, headache, sweating, shakiness, irritability
- Signs of hemophagocytic lymphohistiocytosis: fever, chills, swollen lymph nodes, yellowing of the eyes or skin, nausea, vomiting (throwing up), headache, confusion, trouble breathing, and/or rash

Reproduction Warnings

- **Pregnancy warning:** This medicine can cause serious birth defects. If you can become pregnant, use birth control while taking this medicine and for 4 months after the last dose. If you can get your partner pregnant, use birth control while taking this medicine and for at least 4 months after the last dose, even if you have had a vasectomy. Talk with your care team about effective birth control methods if you are taking trametinib with dabrafenib. Tell your care team right away if you think you might be pregnant or think your partner might be pregnant.
- **Breastfeeding warning:** Do not breastfeed while taking this medicine and for 4 months after the last dose.
- **Fertility warning:** This medicine may affect your ability to have children in the future. If you plan to have children, talk with your care team.

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