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Trametinib

pronounced as (tra me' ti nib)

Why is this medication prescribed?

Trametinib is used alone or in combination with dabrafenib (Tafinlar) to treat a certain types of melanoma (a type of skin cancer) that cannot be treated with surgery or that has spread to other parts of the body. It is used in combination with dabrafenib to treat and prevent the return of a certain type of melanoma after surgery to remove it and any affected lymph nodes. Trametinib is also used in combination with dabrafenib to treat a certain type of non-small-cell lung cancer (NSCLC) that has spread to nearby tissues or to other parts of the body. It is used in combination with dabrafenib to treat a certain type of thyroid cancer that has spread to nearby tissues or to other parts of the body, which cannot be treated with other therapies. Trametinib is in a class of medications called kinase inhibitors. It works by blocking the action of an abnormal protein that signals cancer cells to multiply. This helps stop the spread of cancer cells.

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How should this medicine be used?

Trametinib comes as a tablet to take by mouth. It is usually taken once a day on an empty stomach, at least 1 hour before or 2 hours after a meal. Take trametinib at around the same time every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take trametinib exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor. Do not stop taking trametinib without talking to your doctor.

Your doctor may adjust your dose of trametinib depending on your response to treatment and any side effects that you experience. Talk to your doctor about how you are feeling during your treatment.

Ask your pharmacist or doctor for a copy of the manufacturer's information for the patient.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking trametinib,

- tell your doctor and pharmacist if you are allergic to trametinib, any other medications, or any of the ingredients in trametinib tablets. Ask your pharmacist for a list of the ingredients.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take.
- tell your doctor if you have or have ever had lung disease or breathing problems; diabetes; bleeding problems or blood clots; colitis (inflammation of the colon); stomach problems; high blood pressure; heart, eye, liver, or kidney disease; or any other medical conditions.
- tell your doctor if you are pregnant or plan to become pregnant. You should not become pregnant while you are taking trametinib. You should use birth control to prevent pregnancy during your treatment with trametinib and for 4 months after your final dose. Talk to your doctor about birth control methods that will work for you. If you become pregnant while taking trametinib, call your doctor. Trametinib may harm the fetus.
- tell your doctor if you are breastfeeding or plan to breastfeed. You should not breastfeed while taking trametinib and for 4 months after your final dose.
- you should know that this medication may decrease fertility in women. Talk to your doctor about the risks of taking trametinib.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is less than 12 hours until your next scheduled dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

Trametinib may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- dry skin
- sores on the mouth and tongue
- dry mouth
- vomiting
- loss of appetite
- change in ability to taste food
- tiredness

Some side effects can be serious. If you experience any of these symptoms, stop taking trametinib and call your doctor immediately:

- unusual bleeding or bruising
- bloody or black, tarry stools

- coughing up or vomiting blood or material that looks like coffee grounds
- nosebleed
- severe diarrhea
- stomach pain
- nausea
- fever
- chills
- rapid, irregular, or pounding heartbeat
- difficulty breathing
- chest pain
- swelling of the face, arms, legs, ankles, or feet
- dizziness, lightheadedness, or weakness
- shortness of breath
- leg pain, swelling, tenderness, redness, or warmth
- severe headache
- cough
- blurred vision
- change in vision, including seeing halos (blurred outline around objects) or colored dots
- loss of vision
- eye pain
- dry, red, or swollen eyes
- rash, red skin, or pimples
- wart
- a reddish bump that bleeds or does not heal
- change in size or color of a mole
- itching
- blisters, ulcers, or sores on the skin or nails
- tingling, burning, redness, swelling, peeling or flaking, blisters, or sores on the palms of the hands or soles of the feet
- frequent urination
- increased thirst

Trametinib may increase the risk that you will develop new skin cancers or other cancers. Talk to your doctor about the risks of taking this medication.

Trametinib may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, away from moisture and light, and out of the reach of children. Do not place the tablets in other containers, such as daily or weekly pill boxes. Store it in a refrigerator, but do not freeze it. Do not remove the desiccant (small packet included with medication to absorb moisture) from your bottle.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

Symptoms of overdose may include the following:

- vision problems

What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor will order certain lab tests before and during your treatment to see if it is safe for you to receive trametinib and to check your body's response to trametinib. Your doctor will also check your skin for any changes before you begin treatment, every 2 months during your treatment, and for up to 6 months after treatment. Your doctor will also check your blood pressure from time to time as needed.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Mekinist[®]

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