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Ado-trastuzumab Emtansine Injection

pronounced as (a" doe tras tooz' ue mab em tan' seen)

IMPORTANT WARNING:

Ado-trastuzumab emtansine may cause serious or life-threatening liver problems. Tell your doctor if you have or have ever had liver disease, including hepatitis. Your doctor will order laboratory tests regularly before and during your treatment to see if ado-trastuzumab emtansine is affecting your liver. Your doctor may tell you that you should not receive this medication if the tests show that you have liver problems. Tell your doctor and pharmacist about all the medications you are taking so they can check whether any of your medications may increase the risk that you will develop liver damage during your treatment with ado-trastuzumab emtansine. Call your doctor immediately if you experience any of the following symptoms: nausea, vomiting, extreme tiredness, lack of energy, loss of appetite, pain in the upper right part of the stomach, yellowing of the skin or eyes, dark-colored urine, flu-like symptoms, confusion, drowsiness, or unclear speech.

Ado-trastuzumab emtansine also may cause serious or life-threatening heart problems. Tell your doctor if you have or have ever had heart disease, a heart attack, chest pain, or irregular heartbeats. Your doctor will order tests before and during your treatment to see if your heart is working well enough for you to safely receive ado-trastuzumab emtansine. Your doctor may tell you that you should not receive this medication if the tests show your heart's ability to pump blood has decreased. If you experience any of the following symptoms, call your doctor immediately: cough; shortness of breath; swelling of the arms, hands, feet, ankles or lower legs; weight gain (more than 5 pounds [about 2.3 kilograms] in 24 hours); dizziness; loss of consciousness; or fast, irregular, or pounding heartbeat.

Tell your doctor if you are pregnant or if you or your partner plan to become pregnant. Ado-trastuzumab emtansine may harm your unborn baby. If you can become pregnant, you will need to have a negative pregnancy test before beginning treatment with ado-trastuzumab emtansine. You should use birth control to prevent pregnancy during your treatment and for 7 months after your final dose. If you are a male and your partner can become pregnant, you should use birth control while receiving this medication, and for 4 months after your final dose. Talk to your doctor about birth control methods that will work for you. If you or your partner become pregnant during your treatment with ado-trastuzumab emtansine, call your doctor immediately.

Talk to your doctor about the risks of receiving ado-trastuzumab emtansine injection.

Why is this medication prescribed?

Ado-trastuzumab emtansine injection is used to treat a certain type of breast cancer that has spread to other parts of the body and has not improved or has worsened after treatment with other medications. Ado-trastuzumab emtansine is also used after surgery for a certain type of breast cancer in women who have had treatment with other chemotherapy medications before surgery, but there was still cancer remaining in the tissue removed during surgery. Ado-trastuzumab emtansine is in a class of medications called antibody-drug conjugates. It works by killing cancer cells.

How should this medicine be used?

Ado-trastuzumab emtansine injection comes as a powder to be mixed with liquid and infused (injected slowly) into a vein by a doctor or nurse in a hospital or medical facility. It is usually injected once every 3 weeks. The length of your treatment depends on how well your body responds to the medication and the side effects that you experience.

Ado-trastuzumab emtansine injection may cause serious infusion-related reactions, which may occur during or shortly after the infusion of the medication. It should take 90 minutes for you to receive your first dose of ado-trastuzumab emtansine. A doctor or nurse will watch you closely to see how your body reacts to this medication. If you do not have any serious problems when you receive your first dose of ado-trastuzumab emtansine, it will usually take 30 minutes for you to receive each of your remaining doses of the medication. If you experience any of the following symptoms, tell your doctor immediately: flushing; fever; chills; dizziness; lightheadedness; fainting; shortness of breath; difficulty breathing; or fast, irregular, or pounding heartbeat.

Your doctor may need to delay your treatment, slow down the infusion, or stop your treatment if you experience certain side effects. Be sure to tell your doctor how you are feeling during your treatment with ado-trastuzumab emtansine.

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 receiving ado-trastuzumab emtansine,

- tell your doctor and pharmacist if you are allergic to ado-trastuzumab emtansine, trastuzumab, any other medications, or any of the ingredients in ado-trastuzumab emtansine injection. Ask your doctor or pharmacist for a list of the ingredients.
- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention the medications listed in the IMPORTANT WARNING section and any of the following: apixaban (Eliquis), aspirin (Durlaza, in Aggrenox, others), atazanavir (Reyataz, in Evotaz), cilostazol (Pletal), clarithromycin (Biaxin, in Prevpac), clopidogrel (Plavix), dabigatran (Pradaxa), dalteparin (Fragmin), dipyridamole (Persantine, in Aggrenox), edoxaban (Savaysa), enoxaparin (Lovenox), fondaparinux (Arixtra), heparin, indinavir (Crixivan), itraconazole (Onmel, Sporanox), ketoconazole, nefazodone,

nelfinavir (Viracept), prasugrel (Effient), ritonavir (Norvir, in Kaletra, Technivie, Viekira Pak), rivaroxaban (Xarelto), saquinavir (Invirase), telithromycin (Ketek), ticagrelor (Brilinta), vorapaxar (Zontivity), voriconazole (Vfend), and warfarin (Coumadin, Jantoven). Your doctor may need to change the doses of your medications or monitor you carefully for side effects.

- tell your doctor if you are of Asian descent, or if you have or have ever had any of the conditions mentioned in the IMPORTANT WARNING section, trouble breathing, even when resting, radiation therapy, or any other medical condition.
- tell your doctor if you are breastfeeding. You should not breastfeed while receiving ado-trastuzumab emtansine injection and for 7 months after your final dose.

What special dietary instructions should I follow?

Talk to your doctor about eating grapefruit and drinking grapefruit juice while receiving this medication.

What side effects can this medication cause?

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

- constipation
- diarrhea
- upset stomach
- sores in the mouth and throat
- dry mouth
- changes in ability to taste
- joint or muscle pain
- headache
- dry, red, or teary eyes
- blurry vision
- trouble falling asleep or staying asleep

Some side effects can be serious. If you experience any of these symptoms or those listed in the IMPORTANT WARNING section, call your doctor immediately:

- pain, itching, redness, swelling, blisters, or sores near the place where the medication was injected
- fever, sore throat, chills, difficulty urinating, pain when urinating, and other signs of infection
- nosebleeds and other unusual bleeding or bruising
- bloody or black, tarry stools
- vomiting blood or brown material that resembles coffee grounds
- pain, burning, or tingling in the hands or feet, muscle weakness, trouble moving
- hives

- rash
- itching
- difficulty breathing or swallowing
- nausea; vomiting; loss of appetite; fatigue; rapid heartbeat; dark urine; decreased amount of urine; stomach pain; seizures; hallucinations; or muscle cramps and spasms
- shortness of breath, cough, extreme tiredness

Ado-trastuzumab emtansine may cause other side effects. Call your doctor if you have any unusual problems while receiving 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).

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:

- nosebleeds and other unusual bleeding or bruising
- bloody or black, tarry stools
- vomiting blood or brown material that resembles coffee grounds

What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor will order a lab test before you begin your treatment to see whether your cancer can be treated with ado-trastuzumab emtansine.

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

- Kadcyła[®]

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