





USES

Trastuzumab is used to treat breast cancer.

This medication is given by vein (IV), usually once a week. Medication to prevent side effects may be given before the drug is administered. Follow all instructions for proper mixing, dilution with certain IV fluids and use of this drug. Consult your pharmacist. When mixed with IV fluids this product will be colorless or a clear yellow liquid. Do not give as a rapid IV injection. Check this product visually for particles or discoloration before use. If present, do not use the liquid. Do not mix or dilute with other drugs; consult your pharmacist or nurse.

SIDE EFFECTS

Diarrhea may occur. If this effect persists or worsens, notify your doctor promptly. Report promptly: trouble sleeping, increased coughing, swelling of the hands or feet, bone or joint pain, persistent sore throat, unusual fatigue, pain/redness at the injection site, nausea/vomiting, dizziness, headache. Unlikely but report promptly: tingling hands or feet. This medication can lower the body's ability to fight an infection. Notify your doctor promptly if you develop any signs of an infections such as fever, chills or persistent sore throat. In the unlikely event you have an allergic reaction to this drug, seek immediate medical attention. Symptoms of an allergic reaction include rash, itching, swelling, severe dizziness, or trouble breathing. Symptoms may occur while the drug is being given; in these cases the drug infusion must be stopped. If you notice other effects not listed above, contact your doctor or pharmacist.

PRECAUTIONS

Tell your doctor your medical history, including: any allergies, previous cancer treatments (including radiation therapy to the chest), lung or heart diseases. Do not have immunizations/vaccinations without the consent of your doctor and avoid contact with people who have recently received oral polio vaccine. Tell your doctor if you are pregnant before using this drug. It is not known whether this drug is excreted into breast milk. Because of the potential risk to the infant, breast-feeding while using this drug, or for 6 months after the last dose of this drug, is not recommended. Caution is advised when this drug is used in the elderly, as they may be more sensitive to the side effects of this product.

DRUG INTERACTIONS

Tell your doctor of all nonprescription and prescription medication you may use, especially: current or previous use of other anti-cancer drugs (including doxorubicin, daunorubicin, or cyclophosphamide). Do not mix with dextrosecontaining IV fluids. Do not start or stop any medicine without doctor or pharmacist approval.

OVERDOSE

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly.

MISSED DOSE

It is very important you do not miss any doses. However, if you miss a dose, contact your doctor immediately to establish a new dosing schedule.

STORAGE

Store vials in a refrigerator between 36 and 46 degrees F (2 - 8 degrees C) away from light and moisture. Do not use beyond expiration date stamped on vial. After mixing and dilution with recommended IV fluids, the stability of this product varies. Consult your pharmacist.

WARNING

Use of trastuzumab may lead to serious heart problems, including heart failure. Your doctor may need to stop this medication if these problems occur. Patients who also use anthracyclines (e.g., doxorubicin) and cyclophosphamide are more likely to develop heart problems. Trastuzumab use may also result in several other severe, rarely fatal, problems. Specifically, these are allergic reactions, IV dosing (infusion reaction), and lung disease (acute respiratory distress syndrome-ARDS). These problems, if they occur, usually happen while the drug is being given, or within 24 hours of the dose. The IV dose should be interrupted if you experience trouble breathing, or severe dizziness/very low blood pressure; consult your doctor or pharmacist immediately. Trastuzumab treatment may need to be stopped if severe allergic or lung problems occur; seek immediate medical attention. Read the Side Effects Section carefully. It includes symptoms and advice regarding the medical problems noted in this section.

Note: This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world.



Taj Group of Companies INDIA

Taj Pharmaceuticals Ltd.

Phone : General EPA BX : 91 - (0)22 - 26374592/92 91, (0)22 - 26374592/93 91 - (0)22 - 30601000, Fax: 91-(0)22-26341274

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