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The Bulletin from the Clinical Pharmacist

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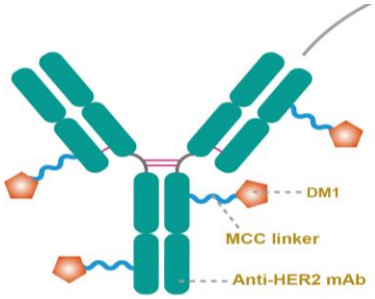

Ado-Trastuzumab Emtansine

Overview: Ado-Trastuzumab Emtansine (T-DM1) is a HER2 targeted antibody drug conjugate (ADC) composed of trastuzumab linked to the cytotoxic agent DM1(Emtansine). It was first approved by the FDA in 2013 for HER2 positive metastatic breast cancer later its indication expanded to adjuvant treatment of patients with HER2-positive early breast cancer in 2019 as the result of KATHERINE trial.

Mechanism of Action: It acts by binding to sub-domain IV of the HER2 receptor, ado-trastuzumab emtansine undergoes receptor-mediated internalization and subsequent lysosomal degradation, resulting in intracellular release of DM1-containing cytotoxic catabolites. Binding of DM1 to tubulin disrupts microtubule networks in the cell, which results in cell cycle arrest and apoptotic cell death.

Indications:

- HER2 Positive early breast cancer (Adjuvant therapy for residual invasive disease after neoadjuvant taxane & trastuzumab based treatment).
- HER2 Positive metastatic breast cancer (Single agent treatment after prior taxane and trastuzumab therapy, or recurrence during or within 6 months of completing adjuvant treatment).

Dosing & Administration: IV: 3.6 mg/kg every 3 weeks. Infuse over 90 minutes (first infusion) or over 30 minutes (subsequent infusions if prior infusions were well tolerated).

Dosage Adjustment:
Altered Kidney Function: There are no dosage adjustments provided in the manufacturer's labeling. Altered Liver Function: Initial or dose adjustment in patients with preexisting liver cirrhosis:
*Child-Turcotte-Pugh class A and B: No dosage adjustment necessary.
*Child-Turcotte-Pugh class C: In general, use not recommended.

Pregnancy & Breastfeeding Considerations: Avoid pregnancy and breastfeeding during treatment and for at least 7 months after the last dose of Ado-Trastuzumab Emtansine.

Adverse Drug Reaction: Hypersensitivity reactions, Infusion reaction, Bone marrow suppression, Left ventricular dysfunction, pulmonary toxicity, Neurotoxicity, Hepatotoxicity, Gastrointestinal symptoms & Peripheral neuropathy.

Monitoring Parameters: HER2 expression status; platelet count, transaminases and bilirubin (at baseline and prior to each dose). Left ventricular function (prior to and at least every 3 months during treatment). Monitor infusion site during infusion for possible infiltration.