

Enhertu® (fam-trastuzumab deruxtecan-nxki): Active and Excipient Mass in Enhertu Vials

Enhertu® (fam-trastuzumab deruxtecan-nxki), also referred to as T-DXd, is an ADC composed of three components: 1) a humanized anti-HER2 IgG1 monoclonal antibody, covalently linked to 2) a topoisomerase inhibitor, via 3) a tetrapeptide-based cleavable linker. Deruxtecan is composed of a protease-cleavable maleimide tetrapeptide linker and the topoisomerase inhibitor, DXd, which is an exatecan derivative. Enhertu is indicated for the treatment of¹:

- adult patients with unresectable or metastatic HER2-positive (IHC 3+ or ISH positive) breast cancer who have received a prior anti-HER2-based regimen either:
 - in the metastatic setting, or
 - in the neoadjuvant or adjuvant setting and have developed disease recurrence during or within six months of completing therapy.
- adult patients with unresectable or metastatic HER2-low (IHC 1+ or IHC 2+/ISH-) breast cancer, as determined by an FDA-approved test, who have received a prior chemotherapy in the metastatic setting or developed disease recurrence during or within 6 months of completing adjuvant chemotherapy.
- adult patients with unresectable or metastatic NSCLC whose tumors have activating HER2 (*ERBB2*) mutations, as detected by an FDA-approved test, and who have received a prior systemic therapy.*
- adult patients with locally advanced or metastatic HER2-positive (IHC 3+ or IHC 2+/ISH positive) gastric or gastroesophageal junction adenocarcinoma who have received a prior trastuzumab-based regimen.
- adult patients with unresectable or metastatic HER2-positive (IHC 3+) solid tumors who have received prior systemic treatment and have no satisfactory alternative treatment options.*

**These indications are approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.*

WARNING: INTERSTITIAL LUNG DISEASE and EMBRYO-FETAL TOXICITY

Interstitial lung disease (ILD) and pneumonitis, including fatal cases, have been reported with ENHERTU. Monitor for and promptly investigate signs and symptoms including cough, dyspnea, fever, and other new or worsening respiratory symptoms. Permanently discontinue ENHERTU in all patients with Grade 2 or higher ILD/pneumonitis. Advise patients of the risk and to immediately report symptoms.

Exposure to ENHERTU during pregnancy can cause embryo-fetal harm. Advise patients of these risks and the need for effective contraception.

For additional information concerning the use of Enhertu, please see the accompanying full Prescribing Information (including **Boxed WARNINGS**), Medication Guide, and Important Safety Information.

The following information is provided in response to your specific inquiry.

Active and Excipient Mass in Enhertu Vials

At a target fill volume of 5.35 mL, the vial contains 107 mg of active fam-trastuzumab deruxtecan-nxki, also referred to as T-DXd, and 510 mg of pharmaceutical excipients due to overfill.²

Abbreviations

ADC: antibody-drug conjugate

ERBB2: Erb-B2 receptor tyrosine kinase 2

FDA: Food and Drug Administration

HER2: human epidermal growth factor receptor 2

IgG1: immunoglobulin G1

IHC: immunohistochemistry

ILD: interstitial lung disease

ISH: in situ hybridization

NSCLC: non-small cell lung cancer

T-DXd: fam-trastuzumab deruxtecan-nxki

References

1. Enhertu® (fam-trastuzumab deruxtecan-nxki) [Prescribing Information]. Daiichi Sankyo, Inc., Basking Ridge, NJ; AstraZeneca Pharmaceuticals LP, Wilmington, DE. Updated 2024.
2. Data on file. Daiichi Sankyo, Inc., Basking Ridge, NJ.