

NEW PRODUCTS

Edited by Lucilla Leung

Enhertu powder
for concentrate for
solution for infusion
(Daiichi Sankyo and AstraZeneca)

Active Ingredients

Trastuzumab deruxtecan

Indication

Breast cancer:

HER2-low breast cancer Enhertu as monotherapy is indicated for the treatment of adult patients with unresectable or metastatic HER2-low breast cancer who have received prior chemotherapy in the metastatic setting or developed disease recurrence during or within 6 months of completing adjuvant chemotherapy.

Gastric cancer:

Enhertu as monotherapy is indicated for the treatment of adult patients with advanced HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma who have received a prior trastuzumab-based regimen.

Dosage and Administration

Breast cancer:

HER2-low breast cancer Patients treated with trastuzumab deruxtecan should have documented HER2-low tumour status, defined as a score of IHC 1+ or IHC 2+/ISH-, as assessed by a CE-marked IVD medical device. If a CE-marked IVD is not available, the HER2 status should be assessed by an alternate validated test

The recommended dose of Enhertu is 5.4 mg/kg given as an intravenous infusion once every 3 weeks (21-day cycle) until disease progression or unacceptable toxicity.

Gastric cancer:

Patients treated with trastuzumab deruxtecan for gastric or gastroesophageal junction cancer should have documented HER2-positive tumour status, defined as a score of 3+ by immunohistochemistry (IHC) or a ratio of ≥ 2 by in situ hybridization (ISH) or by fluorescence in situ hybridization (FISH), assessed by a CE-marked in vitro diagnostic (IVD) medical device. If a CE-marked IVD is not available, the HER2 status should be assessed by an alternate validated test.

The recommended dose of Enhertu is 6.4 mg/kg given as an intravenous infusion once every 3 weeks (21-day cycle) until disease progression or unacceptable toxicity.

The initial dose should be administered as a 90-minute intravenous infusion. If the prior infusion was well tolerated, subsequent doses of Enhertu may be administered as 30-minute infusions. The infusion rate of Enhertu should be slowed or interrupted if the patient develops infusion-related symptoms (see section 4.8). Enhertu should be permanently discontinued in case of severe infusion reactions.

Adverse Reactions

Enhertu 5.4mg/kg

The most common adverse reactions were: nausea (76.8%), fatigue (56.1%), vomiting (44.6%), alopecia (39.1%), anaemia (35.1%), neutropenia (34.4%), constipation (34.3%), decreased appetite (33.1%),

diarrhoea (29.3%), transaminases increased (27.6%), musculoskeletal pain (26.5%), leukopenia (24.3%), and thrombocytopenia (24.2%).

Enhertu 6.4mg/kg The most common adverse reactions were nausea (71.1%), fatigue (58.8%), decreased appetite (53.8%), anaemia (43.5%), neutropenia (42.2%), vomiting (39.1%), diarrhoea (35.5%), alopecia (35.5%), constipation (31.8%), thrombocytopenia (30.5%), leukopenia (28.3%) and transaminases increased (23.7%).

Forensic classification

P1S1S3

Padcev

(Astellas)

Active Ingredients

Enfortumab vedotin

Indication

Monotherapy for locally advanced or metastatic urothelial cancer in adults who have previously received a platinum-containing chemotherapy & a programmed death receptor-1 or programmed death-ligand 1 inhibitor.

Dosage and Administration

IV 1.25 mg/kg (up to max 125 mg for patients ≥ 100 kg) infused over 30 min on days 1, 8, & 15 of a 28-day cycle until disease progression or unacceptable toxicity.

Contraindications

Hypersensitivity to the active ingredients and the excipients.

Adverse Reactions

Anaemia; hyperglycaemia, decreased appetite; peripheral sensory neuropathy, dysgeusia; dry eye; diarrhoea, vomiting, nausea; alopecia, pruritus, rash, rash maculo-papular, dry skin; fatigue; increased ALT &/ or AST, decreased wt. Peripheral neuropathy, peripheral motor neuropathy, peripheral sensorimotor neuropathy, paraesthesia, hypoaesthesia, gait disturbance, muscular weakness; pneumonitis; drug eruption, skin exfoliation, conjunctivitis, dermatitis bullous, blister, stomatitis, palmar-plantar erythrodysesthesia syndrome, eczema, erythema, rash erythematous, rash macular, rash papular, rash pruritic, rash vesicular; infusion site extravasation.

Drug Interactions

Closely monitor for signs of toxicities when receiving concomitant strong CYP3A4 inhibitors (eg, boceprevir, clarithromycin, cobicistat, indinavir, itraconazole, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole). Increased unconjugated microtubule-disrupting agent monomethyl auristatin E (MMAE) C_{max} & AUC exposure w/ ketoconazole (combined P-gp & strong CYP3A inhibitor). Decreased exposure of unconjugated MMAE w/ strong CYP3A4 inducers (eg, rifampicin, carbamazepine, phenobarb, phenytoin, St. John's wort).

Forensic classification

P1S1S3