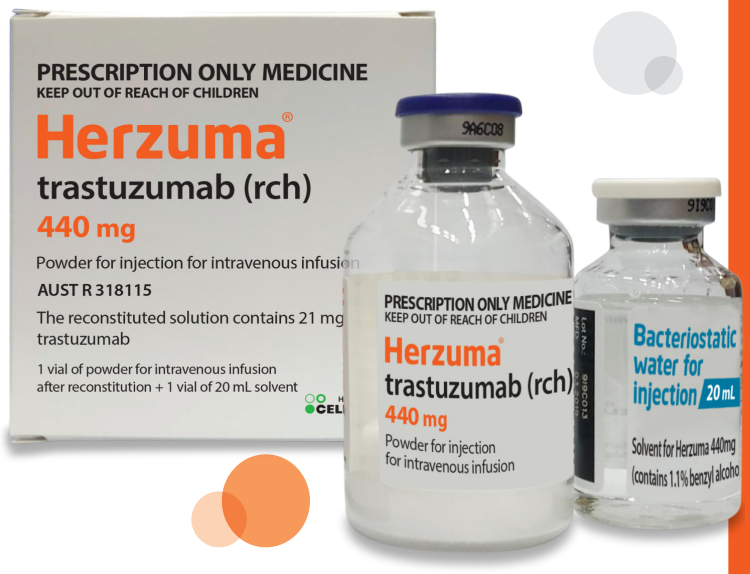
Herzuma®
Trastuzumab

Introducing Herzuma® 440mg PBS Listed from 1 April 2022



Contact Echo Therapeutics for further details and stock availability

Call Jude D'Silva on 0417 944 428 or email customerservice@echotherapeutics.net

PBS Information: Authority Required (STREAMLINED) for the treatment of HER2 - positive breast cancer and HER2 - positive adenocarcinoma of the stomach or gastro-oesophageal junction. Refer to PBS Schedule for full authority information.

Please review full product information before dispensing, available on request from the Celltrion Healthcare Medical Information Service (Phone: 1800 325 228) or via www.ebs.tga.gov.au.

MINIMUM PRODUCT INFORMATION HERZUMA® 150 mg vial contains 150 mg of trastuzumab and HERZUMA® 440 mg vial contains 440 mg of trastuzumab. **INDICATIONS:** For treatment of HER2-positive early breast cancer following surgery, and in association with chemotherapy and, if applicable, radiotherapy; treatment of HER2-positive locally advanced breast cancer in combination with neoadjuvant chemotherapy followed by adjuvant Herzuma; treatment of patients with HER2-overexpressing metastatic breast cancer as monotherapy for the treatment of those patients who have received one or more chemotherapy regimens for their metastatic disease, in combination with taxanes for the treatment of those patients who have not received chemotherapy for their metastatic disease or in combination with an aromatase inhibitor for the treatment of post-menopausal patients with hormone-receptor positive metastatic breast cancer; treatment of advanced gastric cancer in combination with cisplatin and either capecitabine or 5-FU for the treatment of patients with HER2 positive advanced adenocarcinoma of the stomach or gastrooesophageal junction who have not received prior anti-cancer treatment for their metastatic disease. See PI for details. **CONTRAINDICATIONS:** Hypersensitivity to trastuzumab; Chinese hamster ovary cell proteins or to any of its excipients; treatment of early or locally advanced breast cancer, Herzuma is contraindicated in patients with a left ventricular ejection fraction of less than 45% and those with symptomatic heart failure. See PI for details. **PRECAUTIONS:** Not for IV push, bolus admin, SC inj; multiple switches from or to IV treatment (not studied); advanced malignancy, comorbidity associated dyspnoea at rest (should not use); pretreatment physical (especially cardiac) exam, HER2 testing (See full PI); monitor cardiac function including LVEF (pretreatment, every 3 months during treatment, then every 6 months until 24 months (yearly for ≥ 5 yrs if anthracycline therapy) after last dose), for infusion related reaction (IRR); IRRs are known to occur with the administration of trastuzumab (see adverse effects); asymptomatic cardiac dysfunction (monitor 6–8 weekly); cardiac risk for example hypertension (poorly controlled, history), CAD, CHF (or history), diastolic dysfunction, low baseline (< 50%) or declining LVEF (< 55%), prior, concurrent antihypertensives; treatment induced symptomatic heart failure, LVEF reduction by 10% to < 50% withhold therapy; high risk uncontrollable arrhythmia, angina requiring medication, clinically significant valvular disease, MI history, other cardiomyopathy, haemodynamically significant pericardial effusion; prior anthracycline, cyclophosphamide, taxane, gemcitabine, vinorelbine, radiation exposure; use in renal, hepatic impairment is not studied; high cumulative anthracycline dose, BMI > 25 kg/m2 (after adjuvant chemo); age > 50 yrs; women of childbearing potential (ensure adequate contraception), pregnancy, lactation (avoid incl ≥ 7 months after last dose); safety and efficacy of trastuzumab in patients under the age of 18 years have not been established. See PI for details. **INTERACTIONS:** If possible, physicians should avoid anthracycline-based therapy for up to 7 months after stopping trastuzumab; do not admix with dextrose 5%, other medicines. See PI for details. **ADVERSE EFFECTS:** Most common: Nasopharyngitis; infection (for example URTI, catheter); GI upset; dizziness; headache; tremor; nail disorder, toxicity; weight change; decrease appetite; anorexia; insomnia; anxiety; depression; paraesthesia; hypoaesthesia; oedema; hepatic, cardiac (including BP change, arrhythmia, decrease ejection fraction, CHF), wheezing, cough, epistaxis (including pneumonia), haematological (including neutropenia) toxicity; antitrastuzumab Ab formation; hypersensitivity including anaphylaxis, urticaria, angioedema; IRR for example dyspnoea, bronchospasm; hot flush; conjunctivitis; increase lacrimation; dry eye, mouth; erythema; swelling face; palmar plantar erythrodysaesthesia; arthralgia; muscle tightness; myalgia; asthenia; chest pain; chills; fatigue; pancreatitis; others; See PI for details. **DOSAGE AND ADMINISTRATION:** Confirm HER2 status pretreatment. Reconstitute with sterile water for injection (7.2 mL for 150 mg vial) then add required dose to 250 mL NaCl 0.9% infusion solution. Admin by IV infusion: loading dose over approx. 90 min, maintenance doses over 30 min if well tolerated. Early or metastatic breast cancer: for 3 weekly regimen, loading dose: 8 mg/kg followed by maintenance dose 6 mg/kg; for Weekly regimen: loading dose 4 mg/kg followed by maintenance dose of 2 mg/kg. Advanced gastric, locally advanced breast cancer: for 3 weekly regimen: loading dose 8 mg/kg followed by maintenance dose of 6 mg/kg. Missed dose: admin maintenance dose (if less than or equal to 1 week late) or re-loading dose (if > 1 week late) as soon as possible then maintenance doses 7 or 21 days later according to weekly or 3 weekly regimen. Dose modification for IRR: may slow infusion rate or interrupt. Treatment duration: Early or locally advanced breast cancer: maximum 1 yr or until disease recurrence or unmanageable toxicity (whichever occurs first); metastatic breast and advanced gastric cancer: until disease progression or unmanageable toxicity. See PI for details.

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