# Pertuza

Pertuzumab solution for IV infusion

**Presentation**

Pertuza 420: Each vial contains Pertuzumab INN 420 mg in 14 ml solution for IV infusion

**Description**

Pertuzumab is a recombinant humanized monoclonal antibody that targets the extracellular dimerization domain (Subdomain II) of the human epidermal growth factor receptor 2 protein (HER2). Pertuzumab targets the extracellular dimerization domain (Subdomain II) of the human epidermal growth factor receptor 2 protein (HER2) and, thereby, blocks ligand-dependent heterodimerization of HER2 with other HER family members, including EGFR, HER3, and HER4. As a result, Pertuzumab inhibits ligand-initiated intracellular signaling through two major signal pathways, mitogen-activated protein (MAP) kinase, and phosphoinositide 3-kinase (PI3K). Inhibition of these signaling pathways can result in cell growth arrest and apoptosis, respectively. In addition, Pertuzumab mediates antibody-dependent cell-mediated cytotoxicity

**Indications and Uses**

Pertuzumab is a HER2/neu receptor antagonist indicated for:

- Use in combination with Trastuzumab and docetaxel for treatment of patients with HER2-positive metastatic breast cancer (MBC) who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease
- Use in combination with Trastuzumab and docetaxel as neoadjuvant treatment of patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer. This indication is based on demonstration of an improvement in pathological complete response rate. No data are available demonstrating improvement in event-free survival or overall survival

**Limitations of Use:**

The safety of Pertuzumab as part of a doxorubicin-containing regimen has not been established
The safety of Pertuzumab administered for greater than 6 cycles for early breast cancer has not been established

**Dosage and Administration**

For intravenous infusion only. It should not be administered as an intravenous push or bolus
The initial Pertuzumab dose is 840 mg administered as a 60-minute intravenous infusion, followed every 3 weeks thereafter by 420 mg administered as a 30 to 60 minute intravenous infusion
MBC: Pertuzumab should be administered with Trastuzumab and Docetaxel by intravenous infusion every 3 weeks
Neoadjuvant: Pertuzumab should be administered with Trastuzumab and Docetaxel by intravenous infusion preoperatively every 3 weeks for 3 to 6 cycles

**Side-effects**

- Left Ventricular Dysfunction: Pertuzumab can result in subclinical and clinical cardiac failure manifesting as CHF, and decreased LVEF. Evaluate cardiac function prior to and during treatment. Discontinue Pertuzumab treatment for a confirmed clinically significant decrease in left ventricular function
- Embryo-fetal Toxicity: Exposure to Pertuzumab can result in embryo-fetal death and birth defects. Studies in animals have resulted in oligohydramnios, delayed renal development, and death. Patients should be advised of these risks and the need for effective contraception

**Metastatic Breast Cancer**

- The most common adverse reactions (> 30%) with Pertuzumab in combination with Trastuzumab and Docetaxel were diarrhea, alopecia, neutropenia, nausea, fatigue, rash, and peripheral neuropathy

**Neoadjuvant Treatment of Breast Cancer**

- The most common adverse reactions (> 30%) with Pertuzumab in combination with Trastuzumab and Docetaxel were alopecia, diarrhea, nausea, and neutropenia
- The most common adverse reactions (>30%) with Pertuzumab in combination with Trastuzumab and Docetaxel when given for 3 cycles following 3 cycles of fluorouracil, epirubicin, and cyclophosphamide (FEC) were fatigue, alopecia, diarrhea, nausea, vomiting, and neutropenia
- The most common adverse reactions (>30%) with Pertuzumab in combination with Docetaxel, Carboplatin, and Trastuzumab (TCH) were fatigue, alopecia, diarrhea, nausea, vomiting, neutropenia, thrombocytopenia, and anemia

**Contraindications**

Pertuzumab is contraindicated in patients with known hypersensitivity to Pertuzumab or to any of its excipients

**Precaution**

Left Ventricular Dysfunction: LVEF should be monitored and dosing should be withheld as appropriate
Embryo-fetal toxicity: Fetal harm can occur when administered to a pregnant woman
Infusion-Related Reactions: Should be monitored for signs and symptoms. If a significant infusion-associated reaction occurs, the infusion should be slowed or interrupted and appropriate medical therapies should be administered
Hypersensitivity Reactions/Anaphylaxis: Should be monitored for signs and symptoms. If a severe hypersensitivity reaction/anaphylaxis occurs, the infusion should be discontinued immediately and appropriate medical therapies should be administered

**Pregnancy and Lactation**

Pregnancy Category D
There are no adequate and well-controlled studies of Pertuzumab in pregnant women. If Pertuzumab is administered during pregnancy or if a patient becomes pregnant while receiving Pertuzumab or within 7 months following the last dose of Pertuzumab in combination with Trastuzumab, the patient should be apprised of the potential hazard to the fetus

**Lactation**

It is not known whether Pertuzumab is excreted in human milk, but human IgG is excreted in human milk. Because many drugs are secreted in human milk and because of the potential for serious adverse actions in nursing infants from Pertuzumab a decision should be made whether to discontinue nursing, or discontinue drug, taking into account the elimination half-life of Pertuzumab and the importance of the drug to the mother

**Pediatric Use**

Safety and effectiveness of Pertuzumab have not been established in pediatric patients.

**Drug interactions**

Patients who receive anthracycline after stopping Pertuzumab may be at increased risk of cardiac dysfunction because of Pertuzumab's long wash out period. If possible, physicians should avoid anthracycline-based therapy for up to 7 months after stopping Pertuzumab. If anthracyclines are used, the patient's cardiac function should be monitored carefully.

**Instruction of Uses**

Pertuzumab should be administered as an intravenous infusion only. It should not be administered as an intravenous push or bolus. Pertuzumab should not be used with other drugs.

**Preparation**

The solution for infusion should be prepared using aseptic technique, as follows:

- Parenteral drug products should be inspected visually for particulates and discoloration prior to administration
- The appropriate volume of Pertuzumab solution should be withdrawn from the vial(s)
- Pertizumab should be diluted into a 250 mL 0.9% sodium chloride PVC or non-PVC polyolefin infusion bag
- Diluted solution should be mixed by gentle inversion. It should not be shaken
- Pertuzumab should be administered immediately once prepared
- If the diluted infusion solution is not used immediately, it can be stored at 2˚C to 8˚C for up to 24 hours.
- Dilution should be done with 0.9% Sodium Chloride injection only. Dextrose (5%) solution should not be used

**Commercial pack**

Pertuza 420 IV infusion: Each box contains 1 vial of Pertuzumab 420 mg

Manufactured by
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