Tresoda™

Trastuzumab lyophilized powder for IV infusion

2219

Presentation

Tresoda™ 420 Injection: Each vial contains Trastuzumab INN 420 mg as lyophilized cake or powder.

Description

Trastuzumab is a recombinant humanized monoclonal antibody that selectively targets the extracellular domain of the human epidermal growth factor receptor 2 protein (HER2).

Indication and usage

• HER2-overexpressing breast cancer.
• HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma.

Reconstitution

• Using a sterile syringe, 20 mL of Bacteriostatic Water for Injection which contains 0.9% to 1.1% benzyl alcohol as a preservative need to be slowly injected into the vial containing the lyophilized cake or powder of Tresoda. In patients with known hypersensitivity to benzyl alcohol, should be reconstituted with 20 mL of Water for Injection. The stream of diluent must be directed into the lyophilized powder or cake. A solution for multiple-dose use, containing 21 mg/mL Tresoda is yielded from the reconstituted vial.
• The vial needs to be swirled gently to aid reconstitution. Do not shake. The vial needs to be allowed to stand undisturbed for approximately 5 minutes.
• At first the dose (mg) of Tresoda needs to be determined and the required volume of the 21 mg/mL reconstituted Tresoda solution needed must be calculated.
• This amount from the vial must be withdrawn and needs to be added to an infusion bag containing 250 mL of 0.9% Sodium Chloride Injection. Do not use Dextrose (5%) solution.
• The bag needs to be gently inverted to mix the solution.
• The diluted solution of Tresoda in infusion bag should be stored at 2 ^{0}C to 8 ^{0}C upto 24 hours. Do not freeze the solution .

Dosage and administrations

• Adjuvant Treatment of HER2-Overexpressing Breast Cancer Administer at either: Initial dose of 4 mg/kg over 90 minutes IV infusion, then 2 mg/kg over 30 minutes IV infusion weekly for 12 weeks (with paclitaxel or docetaxel) or 18 weeks (with docetaxel/carboplatin). One week after the last weekly dose of Trastuzumab, 6 mg/kg as an IV infusion should be administer over 30 to 90 minutes every three weeks to complete a total of 52 weeks of therapy. Or initial dose of 8 mg/kg over 90 minutes IV infusion, then 6 mg/kg over 30 to 90 minutes IV infusion every three weeks for 52 weeks.
• Metastatic HER2-Overexpressing Breast Cancer: Initial dose of 4 mg/kg as a 90 minutes IV infusion followed by subsequent weekly doses of 2 mg/kg as 30 minutes IV infusions.
• Metastatic HER2-Overexpressing Gastric Cancer: Initial dose of 8 mg/kg over 90 minutes IV infusion, followed by 6 mg/kg over 30 to 90 minutes IV infusion every 3 weeks.

Warnings and precautions

Exacerbation of Chemotherapy-Induced Neutropenia

Contraindications

None

Side-effects

• Adjuvant Breast Cancer: Most common adverse reactions (≥ 5%) are headache, diarrhea, nausea, and chills.
• Metastatic Breast Cancer: Most common adverse reactions (≥ 10%) are fever, chills, headache, infection, congestive heart failure, insomnia, cough, and rash.
• Metastatic Gastric Cancer: Most common adverse reactions (≥ 10%) are neutropenia, diarrhea, fatigue, anemia, stomatitis, weight loss, upper respiratory tract infections, fever, thrombocytopenia, mucosal inflammation, nasopharyngitis, and dysgeusia.

Use in specific populations

Pregnancy: Trastuzumab products can cause fetal harm when administered to a pregnant woman. In post marketing reports, use of trastuzumab during pregnancy resulted in cases of oligohydramnios and of oligohydramnios sequence, manifesting as pulmonary hypoplasia, skeletal abnormalities, and neonatal death.

Lactation: There is no information regarding the presence of trastuzumab products in human milk, the effects on the breastfed infant, or the effects on milk production.
Pediatric Use: The safety and effectiveness of trastuzumab products in pediatric patients have not been established.
Females and Males of Reproductive Potential: Pregnancy status of female's reproductive potential should be verified prior to the initiation of Trastuzumab. Trastuzumab products can cause embryo-fetal harm when administered during pregnancy. Advise females of reproductive potential to use effective contraception during treatment with Trastuzumab and for 7 months following the last dose of Trastuzumab.

Overdosage

There is no experience with overdosage in human clinical trials. Single doses higher than 8 mg/kg have not been tested.

Drug Interaction

There have been no formal drug interaction studies performed with trastuzumab products in humans.

Storage

Store at 2 ^{0}C to 8 ^{0}C in a refrigerator. Do not freeze. Keep out of reach of children.

Commercial pack

Tresoda™ 420 Injection: Each box contains a blister pack containing 1 vial of Trastuzumab 420 mg and 2 ampoules of 10 ml Bacteriostatic Water for Injection and a complimentary pouch comprising of one 20 ml sterile disposable syringe and one infusion set with butterfly needle.

Manufactured by
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