CLAIMS

What is claimed is:

1. A pharmaceutical single-use, unit-dose formulation for intravenous administration to a human to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting, comprising a 5 mL sterile aqueous isotonic solution, said solution comprising:

palonosetron hydrochloride in an amount of 0.25 mg based on the weight of its free base;

from 0.005 mg/mL to 1.0 mg/mL EDTA; and

from 10 mg/mL to 80 mg/mL mannitol,

wherein said formulation is stable at 24 months when stored at room temperature.

2. The pharmaceutical formulation of claim 1, wherein said EDTA is in an amount of 0.5 mg/mL.

3. The pharmaceutical formulation of claim 1, wherein said mannitol is in an amount of 41.5 mg/mL.

4. The pharmaceutical formulation of claim 1, wherein said solution further comprises a citrate buffer.

5. The pharmaceutical formulation of claim 4, wherein said citrate buffer is at a concentration of 20 millimolar.

6. The pharmaceutical formulation of claim 1, wherein said solution is buffered at a pH of 5.0 ± 0.5.

7. The pharmaceutical formulation of claim 1, wherein said EDTA is in an amount of 0.5 mg/mL, wherein said mannitol is in an amount of 41.5 mg/mL,

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wherein said solution further comprises a citrate buffer at a concentration of 20 millimolar, and wherein said solution is buffered at a pH of 5.0 ± 0.5.

8. A pharmaceutical single-use, unit-dose formulation for intravenous administration to a human to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting, comprising a 5 mL sterile aqueous isotonic solution, said solution comprising:

palonosetron hydrochloride in an amount of 0.25 mg based on the weight of its free base;

from 0.005 mg/mL to 1.0 mg/mL EDTA; and

from 10 mg/mL to 80 mg/mL mannitol, wherein said formulation is stable at 18 months when stored at room temperature.

9. A pharmaceutical single-use, unit-dose formulation for intravenous administration to a human to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting, comprising a 50 mL sterile isotonic solution buffered at a pH of 4.8 ± 0.5 comprising:

palonosetron hydrochloride in an amount of 0.75 mg based on the weight of its free base;

450.0 mg sodium chloride;

2.5 mg EDTA;

18.5 mg sodium citrate; and

7.8 mg citric acid monohydrate,

wherein said formulation is contained in a polyethylene multilayer film infusion bag comprising an isoprene rubber stopper.

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