CLAIMS

What is claimed is:

1. A method of treating a patient comprising:

orally administering, to a patient, a solid oral dosage form comprising:

a core comprising a non-ionic polymer matrix, a first amount of ondansetron dispersed within the matrix, and a salt dispersed within the matrix, wherein the first amount of ondansetron ranges from about 9 mg to about 28 mg;

a first seal coat surrounding the core, wherein the first seal coat is comprised of a non-ionic polymer matrix; and

an immediate release drug layer surrounding the first seal coat and comprising a non-ionic polymer and a second amount of ondansetron dispersed therein, wherein the second amount of ondansetron ranges from about 3 mg to about 8 mg,

wherein release of ondansetron from the solid oral dosage form provides exposure to ondansetron for a minimum period of 16 hours so as to result in a reduction in frequency of either vomiting, nausea, diarrhea, or a combination thereof in the patient.

2. The method of claim 1 wherein the solid oral dosage form further comprises an enteric coating surrounding the first seal coat.

3. The method of claim 1 wherein the solid oral dosage form further comprising a second seal coat surrounding the immediate release drug layer, wherein the second seal coat is comprised of a non-ionic polymer.

4. The method of claim 1 wherein the first seal coat of the solid oral dosage form further comprises a coating additive such as plasACRYL™.

5. The method of claim 1 wherein the salt in the core of the solid oral dosage form is dispersed in the matrix at a concentration in the range of 50% to 100% by weight of the matrix.

6. The method of claim 1 wherein release of ondansetron from the solid oral dosage form provides exposure to ondansetron for a minimum period of 20 hours.

7. The method of claim 1 wherein release of ondansetron from the solid oral dosage form provides exposure to ondansetron for a minimum period of 24 hours.

8. The method of claim 1 wherein the solid oral dosage form comprises a first amount of ondansetron of about 9 mg and a second amount of ondansetron of about 3 mg.

9. The method of claim 1 wherein the solid oral dosage form comprises a first amount of ondansetron of about 18 mg and a second amount of ondansetron of about 6 mg.

10. The method of claim 1 wherein the solid oral dosage form comprises a first amount of ondansetron of about 20 mg and a second amount of ondansetron of about 8 mg.

11. The method of claim 1 wherein the solid oral dosage form comprises a first amount of ondansetron of about 28 mg and a second amount of ondansetron of about 8 mg.

12. The method of claim 1 wherein the patient is at least 12 years old, has presumed acute gastroenteritis or acute gastritis, and the solid oral dosage form comprises a first amount of ondansetron of about 18 mg and a second amount of ondansetron of about 6 mg.

13. The method of claim 1 wherein the patient is less than 12 years old, has presumed acute gastroenteritis or acute gastritis, and the solid oral dosage form comprises a first amount of ondansetron of about 9 mg and a second amount of ondansetron of about 3 mg.

14. The method of claim 1 wherein the patient is a female who has been diagnosed with Hyperemesis Gravidarum, and the solid oral dosage form comprises a first amount of ondansetron of about 18 mg and a second amount of ondansetron of about 6 mg.

15. The method of claim 1 wherein the patient is at least 12 years old, has diarrhea predominant irritable bowel syndrome, and the solid oral dosage form comprises a first amount of ondansetron of about 18 mg and a second amount of ondansetron of about 6 mg.

16. The method of claim 1 wherein the patient is less than 12 years old, has diarrhea predominant irritable bowel syndrome, and the solid oral dosage form comprises a first amount of ondansetron of about 9 mg and a second amount of ondansetron of about 3 mg.

CLAIMS

1. Use of ondansetron in the manufacture of a medicament for the treatment of either vomiting, nausea, diarrhea, or a combination thereof, wherein the medicament is a solid oral dosage form comprising:

a core comprising a non-ionic polymer matrix, a first amount of the ondansetron dispersed within the matrix, and an ionizable salt dispersed within the matrix, wherein the first amount of the ondansetron ranges from about 9 mg to about 28 mg;

a first non-functional seal coat surrounding the core, wherein the first non-functional seal coat is comprised of a non-ionic polymer matrix; and

an immediate release drug layer surrounding the first seal coat and comprising a non-ionic polymer and a second amount of the ondansetron dispersed therein, wherein the second amount of the ondansetron ranges from about 3 mg to about 8 mg,

wherein:

a) the first non-functional seal coat does not substantially affect the release of the ondansetron from the solid oral dosage form,

b) the solid oral dosage form yields a burst of ondansetron followed by a zero-order sustained release of ondansetron, and

c) release of the ondansetron from the solid oral dosage form after it has been ingested, provides exposure to the ondansetron for a minimum period of 16 hours so as to result in a reduction in frequency of either vomiting, nausea, diarrhea, or a combination thereof in a patient.

2. The use of claim 1 wherein the solid oral dosage form comprises a first amount of the ondansetron of about 9 mg and a second amount of the ondansetron of about 3 mg.

3. The use of claim 1 wherein the solid oral dosage form comprises a first amount of the ondansetron of about 18 mg and a second amount of the ondansetron of about 6 mg.

4. The use of claim 1 wherein the solid oral dosage form comprises a first amount of the ondansetron of about 20 mg and a second amount of the ondansetron of about 8 mg.

5. The use of claim 1 wherein the solid oral dosage form comprises a first amount of the ondansetron of about 28 mg and a second amount of the ondansetron of about 8 mg.

6. The use of claim 1 wherein the patient is at least 12 years old, has presumed acute gastroenteritis or acute gastritis, and the solid oral dosage form comprises a first amount of the ondansetron of about 18 mg and a second amount of the ondansetron of about 6 mg.

7. The use of claim 1 wherein the patient is at least 12 years old, has diarrhea predominant irritable bowel syndrome, and the solid oral dosage form comprises a first amount of the ondansetron of about 18 mg and a second amount of the ondansetron of about 6 mg.

8. The use of claim 1 wherein the patient is less than 12 years old, has diarrhea predominant irritable bowel syndrome, and the solid oral dosage form comprises a first amount of the ondansetron of about 9 mg and a second amount of the ondansetron of about 3 mg.

9. The use of claim 1 wherein upon administration following a single oral administration of the dosage form in adults under fasted conditions provides a median time to maximum plasma concentration (T_{max}) of ondansetron of about 4 hours and a mean maximum plasma concentration (C_{max}) which is more than two times the mean plasma level of the ondansetron at about 24 hours (C_{24}) after administration of the dosage form, and which dosage form provides effective treatment for at least 24 hours after administration to the patient.

10. The use of claim 1 further comprising a second non-functional seal coat surrounding the immediate release drug layer, wherein the second non-functional seal coat is comprised of a non-ionic polymer matrix, and wherein the second non-functional seal coat does not substantially affect the release of the ondansetron from the solid oral dosage form.