Claims

1. A dosage form comprising a dose of N-acetylhomotaurinate, its calcium salt, or another pharmaceutically acceptable salt thereof dispersed in a polymeric matrix comprising at least one or more polymers that is an acrylic polymer~~, wherein upon administration to the subject, the dosage form provides a mean Cmax of plasma acamprosate which is about 20% to about 50% lower than the mean Cmax of plasma acamprosate provided by an oral immediate release (IR) dosage form of equal dose~~.

~~2. A dosage form comprising a dose of N-acetylhomotaurinate, its calcium salt, or another pharmaceutically acceptable salt thereof dispersed in a polymeric matrix, wherein upon administration to the subject, the dosage form, when administered to dogs, provides a median Tmax which is about 2 hours to about 7 hours greater than the Tmax provided by an oral immediate release (IR) dosage form of equal dose.~~

2~~3~~. The dosage form of claim 1, wherein the dose of acamprosate is ~~about~~ 50 mg to ~~less than~~ 1 gram.

3~~4~~. The dosage form of claim 1, wherein 90% or more of the dose of acamprosate is released from the dosage form ~~after about~~ within 8 hours after administration.

~~5. The dosage form of claim 1, wherein the dosage form comprises at least one or more polymers that is an acrylic polymer.~~

4. The dosage form of claim 1, wherein the acrylic polymer is a carbomer.

5. The dosage form of claim 4, wherein the carbomer is a homopolymer type B.

6. A pharmaceutical dosage form comprising:

a dose of N-acetylhomotaurinate, its calcium salt, or another pharmaceutically acceptable salt thereof within the range of 50 mg to 1 g; and

one or more polymers selected from a carbomer homopolymer type B, and carboxymethylcellulose;

wherein upon administration to the subject, the dosage form provides one or more of:

a mean AUC of plasma acamprosate equal to or significantly lower than the mean AUC of plasma acamprosate provided by an immediate release (IR) dosage form which contains a dose of acamprosate or pharmaceutically acceptable salt thereof equal to the dose of in the dosage form;

a mean C_{max} of plasma acamprosate less than the mean C_{max} of plasma acamprosate provided by the IR dosage form;

a median T_{max} of plasma acamprosate greater than the median T_{max} of plasma acamprosate provided by the IR dosage form;

residence time above a therapeutic threshold for a period of time between 1.5 and 4 times longer than that observed with IR dosing; and

concentration greater than 50% of Cmax for 4-8 hours;

a pK curve after a single dose characterized by a residence time above a therapeutic threshold of sufficient length that at least 40-90% of AUC for a 24 hour period after the single dose is attributable to time above the threshold.

7. The pharmaceutical dosage form of claim 6~~1~~, wherein the residence time above a threshold is above a threshold that represent ~~about~~ 15 – 40% of the daily exposure time following a dose but ~~about~~ 40 to 90% of the AUC_{0-24}.

8. The pharmaceutical dosage form of claim 6~~5~~, wherein the residence time above a threshold is for a period of time between 1.5 and 4 times longer than that observed with IR dosing. ~~wherein the acrylic polymer is a carbomer~~.

9. The pharmaceutical dosage form of claim 6~~8~~, wherein the ~~carbomer~~ polymer is a carbomer homopolymer type B.

10. A pharmaceutical dosage form comprising:

a dose of N-acetylhomotaurinate, its calcium salt, or another pharmaceutically acceptable salt thereof within the range of 50 mg to 1 g; and

one or more polymers selected from a carbomer homopolymer type B and carboxymethylcellulose;

wherein upon administration to the subject, the dosage form provides one or more of:

a mean AUC of plasma acamprosate equal to or significantly lower than the mean AUC of plasma acamprosate provided by an immediate release (IR) dosage form which contains a dose of acamprosate or pharmaceutically acceptable salt thereof equal to the dose of in the dosage form;

a mean C_{max} of plasma acamprosate less than the mean C_{max} of plasma acamprosate provided by the IR dosage form;

a median T_{max} of plasma acamprosate greater than the median T_{max} of plasma acamprosate provided by the IR dosage form;

release of 90% or more of the acamprosate or pharmaceutically acceptable salt thereof within 8 hours;

residence time above a therapeutic threshold for a period of time between 1.5 and 4 times longer than that observed with IR dosing;

concentration greater than 50% of Cmax for 4-8 hours; and

steady concentration for only part of a 24 hour period, which part is about 4-8 hours.

11. The pharmaceutical dosage form of claim 10~~1~~, wherein the residence time above a threshold is for a period of time between 1.5 and 4 times longer than that observed with IR dosing.

12. Use of a dosage form for the preparation of a medicament for treating tardive dyskinesia and other movement disorders induced by chronic exposure of patients to neuroleptic (antipsychotic) drugs, Tourette syndrome, posttraumatic stress disorder (PTSD) and obsessive-compulsive disorder (OCD), wherein the dosage form comprises~~ing~~ a dose of N-acetylhomotaurinate, its calcium salt, or another pharmaceutically acceptable salt thereof dispersed in a polymeric matrix comprising at least one or more polymers that is an acrylic polymer~~in the preparation of a medicament for treating a neuropsychiatric disorder, wherein the dosage form is to be administered to a subject to provide a mean Cmax of plasma acamprosate which is about 20% to about 50% lower than the mean Cmax of plasma acamprosate provided by an oral immediate release (IR) dosage form of equal dose.~~

~~13. Use of a dosage form comprising a dose of N-acetylhomotaurinate, its calcium salt, or another pharmaceutically acceptable salt thereof dispersed in a polymeric matrix in the preparation of a medicament for treating a neuropsychiatric disorder, wherein the dosage form is to be administered to dogs to provide a median Tmax which is about 2 hours to about 7 hours greater than the Tmax provided by an oral immediate release (IR) dosage form of equal dose.~~

13~~14~~. The use of claim 12, wherein the dose of acamprosate is ~~about~~ 50 mg to ~~less than~~ 1 gram.

14~~15~~. The use of claim 12, wherein 90% or more of the dose of acamprosate is released from the dosage form ~~after about~~within 8 hours after administration.

~~16. The use of claim 12, wherein the dosage form comprises at least one or more polymers that is an acrylic polymer.~~

15. The use of claim 12, wherein the acrylic polymer is a carbomer.

16. The use of claim 15, wherein the carbomer is a homopolymer type B.

17. The use of claim 12, wherein the dosage form is to be administered to the subject to provide a residence time above a threshold which is above a threshold that represents 15 – 40% of the daily exposure time following a dose but 40 to 90% of AUC_{0-24}.

18. The use of claim 12, wherein the dosage form is to be administered to the subject to provide a residence time above a threshold for a period of time between 1.5 and 4 times longer than that observed with IR dosing.

1917. Use of a pharmaceutical dosage form forin the preparation of a medicament for treating tardive dyskinesia and other movement disorders induced by chronic exposure of patients to neuroleptic (antipsychotic) drugs, Tourette syndrome, posttraumatic stress disorder (PTSD) and obsessive-compulsive disorder (OCD)a neuropsychiatric disorder, wherein the pharmaceutical dosage form comprises:

a dose of N-acetylhomotaurinate, its calcium salt, or another pharmaceutically acceptable salt thereof within the range of 50 mg to 1 g; and

one or more polymers selected from a carbomer homopolymer type B, and carboxymethylcellulose; and

wherein the dosage form is to be administered to a subject to provide one or more of:

a mean AUC of plasma acamprosate equal to or significantly lower than the mean AUC of plasma acamprosate provided by an immediate release (IR) dosage form which contains a dose of acamprosate or pharmaceutically acceptable salt thereof equal to the dose of in the dosage form;

a mean C_{max} of plasma acamprosate less than the mean C_{max} of plasma acamprosate provided by the IR dosage form;

a median T_{max} of plasma acamprosate greater than the median T_{max} of plasma acamprosate provided by the IR dosage form;

residence time above a therapeutic threshold for a period of time between 1.5 and 4 times longer than that observed with IR dosing; and

~~concentration greater than 50% of Cmax for 4-8 hours;~~

~~a pK curve after a single dose characterized by a residence time above a therapeutic threshold of sufficient length that at least 40-90% of AUC for a 24 hour period after the single dose is attributable to time above the threshold~~.

20~~18~~. The use of claim 19~~12~~, wherein the pharmaceutical dosage form is to be administered to the subject to provide a residence time above a threshold which is above a threshold that represents ~~about~~ 15 – 40% of the daily exposure time following a dose but ~~about~~ 40 to 90% of AUC_{0-24}.

~~19. The use of claim 16, wherein the acrylic polymer is a carbomer.~~

21~~20~~. The use of claim 19, wherein the ~~carbomer~~ polymer is a carbomer homopolymer type B.

~~21. Use of a pharmaceutical dosage form in the preparation of a medicament for treating a neuropsychiatric disorder, wherein the pharmaceutical dosage form comprises:~~

~~a dose of N-acetylhomotaurinate, its calcium salt, or another pharmaceutically acceptable salt thereof within the range of 50 mg to 1 g; and~~

~~one or more polymers selected from a carbomer homopolymer type B and carboxymethylcellulose; and~~

~~wherein the dosage form is to be administered to a subject to provide one or more of:~~

~~a mean AUC of plasma acamprosate equal to or significantly lower than the mean AUC of plasma acamprosate provided by an immediate release (IR) dosage form which contains a dose of acamprosate or pharmaceutically acceptable salt thereof equal to the dose of in the dosage form;~~

~~a mean C_{max} of plasma acamprosate less than the mean C_{max} of plasma acamprosate provided by the IR dosage form;~~

~~a median T_{max} of plasma acamprosate greater than the median T_{max} of plasma acamprosate provided by the IR dosage form;~~

~~release of 90% or more of the acamprosate or pharmaceutically acceptable salt thereof within 8 hours;~~

~~residence time above a therapeutic threshold for a period of time between 1.5 and 4 times longer than that observed with IR dosing;~~

~~concentration greater than 50% of Cmax for 4-8 hours; and~~

~~steady concentration for only part of a 24 hour period, which part is about 4-8 hours.~~

22. The use of claim 19~~12~~, wherein the pharmaceutical dosage form is to be administered to the subject to provide a residence time above a threshold for a period of time between 1.5 and 4 times longer than that observed with IR dosing.

23. A composition comprising acamprosate or a pharmaceutically acceptable salt thereof at a dosage of 350 mg to 900 mg and 5% to 20% of carbomer homopolymer type B based on the total weight of the composition.

Claims

1. A dosage form comprising a dose of N-acetylhomotaurinate, its calcium salt, or another pharmaceutically acceptable salt thereof dispersed in a polymeric matrix comprising at least one or more polymers that is an acrylic polymer.

2. The dosage form of claim 1, wherein the dose of acamprosate is 50 mg to 1 gram.

3. The dosage form of claim 1, wherein 90% or more of the dose of acamprosate is released from the dosage form within 8 hours after administration.

4. The dosage form of claim 1, wherein the acrylic polymer is a carbomer.

5. The dosage form of claim 4, wherein the carbomer is a homopolymer type B.

6. A pharmaceutical dosage form comprising:

a dose of N-acetylhomotaurinate, its calcium salt, or another pharmaceutically acceptable salt thereof within the range of 50 mg to 1 g; and

one or more polymers selected from a carbomer homopolymer type B, and carboxymethylcellulose;

wherein upon administration to the subject, the dosage form provides one or more of:

a mean AUC of plasma acamprosate equal to or significantly lower than the mean AUC of plasma acamprosate provided by an immediate release (IR) dosage form which contains a dose of acamprosate or pharmaceutically acceptable salt thereof equal to the dose of in the dosage form;

a mean C_{max} of plasma acamprosate less than the mean C_{max} of plasma acamprosate provided by the IR dosage form;

a median T_{max} of plasma acamprosate greater than the median T_{max} of plasma acamprosate provided by the IR dosage form;

residence time above a therapeutic threshold for a period of time between 1.5 and 4 times longer than that observed with IR dosing; and

concentration greater than 50% of Cmax for 4-8 hours;

a pK curve after a single dose characterized by a residence time above a therapeutic threshold of sufficient length that at least 40-90% of AUC for a 24 hour period after the single dose is attributable to time above the threshold.

7. The pharmaceutical dosage form of claim 6, wherein the residence time above a threshold is above a threshold that represent 15 – 40% of the daily exposure time following a dose but 40 to 90% of the AUC_{0-24}.

8. The pharmaceutical dosage form of claim 6, wherein the residence time above a threshold is for a period of time between 1.5 and 4 times longer than that observed with IR dosing. .

9. The pharmaceutical dosage form of claim 6, wherein the polymer is a carbomer homopolymer type B.

10. A pharmaceutical dosage form comprising:

a dose of N-acetylhomotaurinate, its calcium salt, or another pharmaceutically acceptable salt thereof within the range of 50 mg to 1 g; and

one or more polymers selected from a carbomer homopolymer type B and carboxymethylcellulose;

wherein upon administration to the subject, the dosage form provides one or more of:

a mean AUC of plasma acamprosate equal to or significantly lower than the mean AUC of plasma acamprosate provided by an immediate release (IR) dosage form which contains a dose of acamprosate or pharmaceutically acceptable salt thereof equal to the dose of in the dosage form;

a mean C_{max} of plasma acamprosate less than the mean C_{max} of plasma acamprosate provided by the IR dosage form;

a median T_{max} of plasma acamprosate greater than the median T_{max} of plasma acamprosate provided by the IR dosage form;

release of 90% or more of the acamprosate or pharmaceutically acceptable salt thereof within 8 hours;

residence time above a therapeutic threshold for a period of time between 1.5 and 4 times longer than that observed with IR dosing;

concentration greater than 50% of Cmax for 4-8 hours; and

steady concentration for only part of a 24 hour period, which part is about 4-8 hours.

11. The pharmaceutical dosage form of claim 10, wherein the residence time above a threshold is for a period of time between 1.5 and 4 times longer than that observed with IR dosing.

12. Use of a dosage form for the preparation of a medicament for treating tardive dyskinesia and other movement disorders induced by chronic exposure of patients to neuroleptic (antipsychotic) drugs, Tourette syndrome, posttraumatic stress disorder (PTSD) and obsessive-compulsive disorder (OCD), wherein the dosage form comprises a dose of N-acetylhomotaurinate, its calcium salt, or another pharmaceutically acceptable salt thereof dispersed in a polymeric matrix comprising at least one or more polymers that is an acrylic polymer.

13. The use of claim 12, wherein the dose of acamprosate is 50 mg to 1 gram.

14. The use of claim 12, wherein 90% or more of the dose of acamprosate is released from the dosage form within 8 hours after administration.

15. The use of claim 12, wherein the acrylic polymer is a carbomer.

16. The use of claim 15, wherein the carbomer is a homopolymer type B.

17. The use of claim 12, wherein the dosage form is to be administered to the subject to provide a residence time above a threshold which is above a threshold that represents 15 – 40% of the daily exposure time following a dose but 40 to 90% of AUC_{0-24}.

18. The use of claim 12, wherein the dosage form is to be administered to the subject to provide a residence time above a threshold for a period of time between 1.5 and 4 times longer than that observed with IR dosing.

19. Use of a pharmaceutical dosage form for the preparation of a medicament for treating tardive dyskinesia and other movement disorders induced by chronic exposure of patients to neuroleptic (antipsychotic) drugs, Tourette syndrome, posttraumatic stress disorder (PTSD) and obsessive-compulsive disorder (OCD), wherein the pharmaceutical dosage form comprises:

a dose of N-acetylhomotaurinate, its calcium salt, or another pharmaceutically acceptable salt thereof within the range of 50 mg to 1 g; and

one or more polymers selected from a carbomer homopolymer type B, and carboxymethylcellulose.

20. The use of claim 19, wherein the pharmaceutical dosage form is to be administered to the subject to provide a residence time above a threshold which is above a threshold that represents 15 – 40% of the daily exposure time following a dose but 40 to 90% of AUC_{0-24}.

21. The use of claim 19, wherein the polymer is a carbomer homopolymer type B.

22. The use of claim 19, wherein the pharmaceutical dosage form is to be administered to the subject to provide a residence time above a threshold for a period of time between 1.5 and 4 times longer than that observed with IR dosing.

23. A composition comprising acamprosate or a pharmaceutically acceptable salt thereof at a dosage of 350 mg to 900 mg and 5% to 20% of carbomer homopolymer type B based on the total weight of the composition.