Claims:

Claim 1. A sublingual composition for treating agitation or the signs of agitation in a subject, comprising an effective amount of Dexmedetomidine or a pharmaceutically acceptable salt thereof and one or more pharmaceutically acceptable carriers/excipients, wherein the agitation is associated with a neurodegenerative and/or neuropsychiatric disease, and wherein the composition does not cause significant sedation within about 60 minutes after administration.

Claim 2. The sublingual composition according to Claim 1, wherein the agitation is associated with a neurodegenerative disease.

Claim 3. The sublingual composition according to Claim 2, wherein said neurodegenerative disease is selected from the group consisting of Alzheimer disease, frontotemporal dementia (FTD), dementia, dementia with Lewy bodies (DLB), post-traumatic stress disorder, Parkinson's disease, vascular dementia, vascular cognitive impairment, Huntington's disease, multiple sclerosis, Creutzfeldt-Jakob disease, multiple system atrophy, and progressive supranuclear palsy.

Claim 4. The sublingual composition according to Claim 3, wherein said neurodegenerative disease is selected from the group consisting of dementia, frontotemporal dementia, Alzheimer’s disease and Parkinson’s disease.

Claim 5. The sublingual composition according to Claim 1, wherein the agitation is associated with a neuropsychiatric disease.

Claim 6. The sublingual composition according to Claim 5, wherein said neuropsychiatric disease is selected from the group consisting of schizophrenia, bipolar disorder, bipolar mania, delirium, and depression.

Claim 7. The sublingual composition according to Claim 1, wherein the composition is a dosage form selected from the group consisting of a film, wafer, patch, lozenge, gel, spray, tablet and liquid drops.

Claim 8. The sublingual composition according to Claim 7, wherein said dosage form is a film and the film is a thin film.

Claim 9. The sublingual composition according to Claim 7 or Claim 8, wherein said film is mucoadhesive in nature and provides a quick onset of action.

Claim 10. The sublingual composition according to Claim 2, wherein the composition is a dosage form selected from the group consisting of a film, wafer, patch, lozenge, gel, spray, tablet and liquid drops.

Claim 11. The sublingual composition according to Claim 10, wherein said dosage form is a film and the film is a thin film.

Claim 12. The sublingual composition according to Claim 10 or Claim 11, wherein said film is mucoadhesive in nature and provides a quick onset of action.

Claim 13. The sublingual composition according to Claim 5, wherein the composition is a dosage form is selected from the group consisting of a film, wafer, patch, lozenge, gel, spray, tablet and liquid drops.

Claim 14. The sublingual composition according to Claim 13, wherein said dosage form is a film and the film is a thin film.

Claim 15. The sublingual composition according to Claim 13 or Claim 14, wherein said film is mucoadhesive in nature and provides a quick onset of action.

Claim 16. The sublingual composition according to Claim 7 or Claim 8, wherein said composition comprises Dexmedetomidine or a pharmaceutically acceptable salt thereof at a dosage in the range of about 3 micrograms to about 100 micrograms.

Claim 17. The sublingual composition according to Claim 16, wherein said dosage is about 5 micrograms to about 30 micrograms.

Claim 18. The sublingual composition according to Claim 10 or Claim 11, wherein said composition comprises Dexmedetomidine or a pharmaceutically acceptable salt thereof at a dosage in the range of about 3 micrograms to about 100 micrograms.

Claim 19. The sublingual composition according to Claim 18, wherein said dosage is about 5 micrograms to about 30 micrograms.

Claim 20. The sublingual composition according to Claim 13 or Claim 14, wherein said composition comprises Dexmedetomidine or a pharmaceutically acceptable salt thereof at a dosage in the range of about 3 micrograms to about 100 micrograms.

Claim 21. The sublingual composition according to Claim 20, wherein said dosage is about 5 micrograms to about 30 micrograms.

Claim 22. The sublingual composition according to claim 1, which upon administration produces a therapeutic effect to suppress agitation in about 30 seconds to about 30 minutes without causing significant sedation.

Claim 23. A sublingual composition for treating agitation or the signs of agitation in a subject, comprising an effective amount of Dexmedetomidine or a pharmaceutically acceptable salt thereof, wherein said agitation is not perioperative agitation, wherein the agitation is associated with a

neurodegenerative and/or neuropsychiatric disease, and wherein the composition does not cause significant sedation within about 60 minutes after administration.

Claim 24. A sublingual composition for treating agitation or the signs of agitation in a subject, comprising an effective amount of Dexmedetomidine or a pharmaceutically acceptable salt thereof, wherein said agitation is associated with substance abuse withdrawal, and wherein the composition does not cause significant sedation within about 60 minutes after administration.

Claim 25. The sublingual composition according to any one of claims 1-24, wherein the agitation includes aggression.

Claim 26. The sublingual composition according to any one of claims 1-24, wherein the agitation is acute agitation.

Claim 27. The sublingual composition according to any one of claims 1 to 24, wherein the agitation is chronic agitation.

Claim 28. The sublingual composition according to any one of claims 1 to 24, wherein the agitation is severe agitation.

Claim 29. A sublingual composition for treating agitation or symptoms of agitation in a subject, which is a film comprising an effective amount of dexmedetomidine or a pharmaceutically acceptable salt thereof and one or more pharmaceutically acceptable carriers / excipients, wherein the agitation is associated with a neurodegenerative and/or neuropsychiatric disease, and wherein the composition does not cause significant sedation within about 60 minutes after administration.

Claim 30. The sublingual composition of claim 29, wherein the film is mucoadhesive in nature and provides a rapid onset of action.

Claim 31. The sublingual composition of any one of claims 1 to 30, wherein dexmedetomidine or a pharmaceutically acceptable salt thereof is present as dexmedetomidine hydrochloride.