CLAIMS

1. An oral dosage form comprising:

a core; and

a delayed-release coating that surrounds the core,

wherein the core comprises pitolisant or a pharmaceutically acceptable salt, solvate, or hydrate thereof; an alkaline agent, and optionally one or more pharmaceutically acceptable excipients.

2. The dosage form of claim 1, wherein the core comprises pitolisant monohydrochloride.

3. The dosage form of claim 1 or 2, wherein the alkaline agent is selected from the group consisting of magnesium carbonate, potassium bicarbonate, and sodium carbonate.

4. The dosage form of any one of the preceding claims, wherein the delayed-release coating comprises a polymer, optionally wherein the polymer comprises an ionizable functional group (e.g., a carboxylic acid group).

5. The dosage form of any one of the preceding claims, wherein the delayed-release coating comprises a cellulosic material (e.g., an alkylcellulose), an acrylic or acrylate polymer, or a methacrylic or methacrylate copolymer (e.g., an anionic methacrylate copolymer), such as ACRYL-EZE®.

6. The dosage form of any one of the preceding claims, wherein the delayed-release coating comprises a plasticizer, such as polyethylene glycol (PEG), e.g., PEG8000, or triethyl citrate.

7. The dosage form of any one of the preceding claims, further comprising an anti-moisture barrier such as an OPADRY® polymer, e.g., OPADRY® amb II, preferably positioned between the core and the delayed-release coating.

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8. The dosage form of any one of the preceding claims, comprising between about 1 mg and about 100 mg pitolisant or a pharmaceutically acceptable salt, solvate, or hydrate thereof (e.g., between about 1 mg and about 80 mg, between about 1 mg and about 40 mg, between about 1 mg and about 40 mg, between about 20 mg and about 40 mg, between about 40 mg and about 60 mg, or between about 50 mg and about 70 mg), preferably about 40 mg of pitolisant or a pharmaceutically acceptable salt, solvate, or hydrate thereof.

9. The dosage form of any one of the preceding claims, comprising about 7.5 mg or about 30 mg of an alkaline agent.

10. The dosage form of any one of the preceding claims, comprising at least one pharmaceutically acceptable excipient preferably selected from the group consisting of lactose, microcrystalline cellulose, croscarmellose sodium, magnesium stearate, and colloidal silica (e.g., anhydrous colloidal silica).

11. The dosage form of any one of the preceding claims, wherein the pitolisant or a pharmaceutically acceptable salt, solvate, or hydrate thereof is crystalline pitolisant monohydrochloride.

12. The dosage form of any one of the preceding claims, wherein the core comprises (e.g., consists essentially of, e.g., consists of) pitolisant monohydrochloride, an alkaline agent, lactose, microcrystalline cellulose, croscarmellose sodium, magnesium stearate, and colloidal silica (e.g., anhydrous colloidal silica).

13. The dosage form of any one of the preceding claims, wherein the pitolisant or a pharmaceutically acceptable salt, solvate, or hydrate thereof has an X-ray diffractogram that comprises characteristic peaks (2θ) at 11.2°, 19.9°, 20.7°, and 34.1° (± 0.2°), preferably comprises characteristic peaks (2θ) at 11.2°, 15.4°, 16.3°, 16.9°, 17.8°, 19.9°, 20.7°, 21.0°, 21.8°, 22.6°, 24.5°, 24.6°, 25.0°, 25.5°, 26.3°, 28.3°, 30.3°, 34.1°, 35.8°, 40.0°, and 46.0° (± 0.2°).

14. The dosage form of any one of the preceding claims, wherein the oral dosage form is a tablet.

15. The dosage form of any one of the preceding claims, wherein the dosage form is bioequivalent to a dosage form comprising pitolisant or a pharmaceutically acceptable salt, solvate, or hydrate thereof, in the same amount, that does not comprise a delayed release coating (e.g., WAKIX®), or wherein the dosage form provides a superior bioavailability of pitolisant (e.g., an increase in bioavailability of about 5%, about 10%, about 20%, or greater).

16. The dosage form of any one of the preceding claims, wherein the dosage form provides a superior bioavailability of pitolisant (e.g., an increase in bioavailability of about 5%, about 10%, about 20%, or greater) compared to a dosage form comprising pitolisant or a pharmaceutically acceptable salt, solvate, or hydrate thereof (e.g., in the same amount) that does not comprise a delayed-release coating (e.g., WAKIX®) or an alkaline agent.

17. The dosage form according to any one of claims 1 to 16 which is chosen from formulations A, B, C and D :

Formulation A (in mg/unit)

Pitolisant HCl : 40.00

Magnesium carbonate : 30.00

Lactose : 107.17

Microcrystalline cellulose : 53.58

Croscarmellose sodium :11.25

Anhydrous colloidal silica : 2.00

Magnesium stearate : 6.00

Coating

Opadry amb II (clear, 88A190022) : 7.5

Acryl Eze 93A19346 clear : 38.625

PEG 8000 : 3.09

Formulation B (in mg/unit)

Pitolisant HCl : 40.00

Magnesium carbonate : 7.50

Lactose : 122.17

Microcrystalline cellulose : 61.08

Croscarmellose sodium :11.25

Anhydrous colloidal silica : 2.00

Magnesium stearate : 6.00

Coating

Opadry amb II (clear, 88A190022) : 7.5

Acryl Eze 93A19346 clear : 38.625

PEG 8000 : 3.09

Formulation C (in mg/unit)

Pitolisant HCl : 40.00

Potassium bicarbonate : 30.00

Lactose : 107.17

Microcrystalline cellulose : 53.58

Croscarmellose sodium : 11.25

Anhydrous colloidal silica : 2.00

Magnesium stearate : 6.00

Coating

Opadry amb II (clear, 88A190022) : 7.5

Acryl Eze 93A19346 clear : 38.625

PEG 8000 : 3.09

Formulation D (in mg/unit)

Pitolisant HCl : 40.00

Sodium carbonate : 30.00

Lactose : 107.17

Microcrystalline cellulose : 53.58

Croscarmellose sodium : 11.25

Anhydrous colloidal silica : 2.00

Magnesium stearate : 6.00

Coating

Opadry amb II (clear, 88A190022) : 7.5

Acryl Eze 93A19346 clear : 38.625

PEG 8000 : 3.09.

18. A dosage form (e.g., oral dosage form) of any one of claims 1 to 17, for use in the treatment of a disease or disorder, such as a sleep disorder, optionally, wherein the disease or disorder is fatigue, excessive daytime sleepiness (EDS), cataplexy, narcolepsy, sleep apnea (e.g., obstructive sleep apnea), sleep induced apnea, or diurnal somnolence.

19. The dosage form for use of claim 18, wherein the disease or disorder is in a subject with narcolepsy (e.g., an adult subject with narcolepsy).

20. A method of making an oral dosage form of any one of claims 1 to 17.

21. The method of claim 20, comprising the steps of:

a) blending pitolisant or a pharmaceutically acceptable salt, solvate, or hydrate thereof, and an alkaline agent (e.g., magnesium carbonate, potassium bicarbonate, or sodium carbonate), with one or more pharmaceutically acceptable excipients (e.g., lactose, microcrystalline cellulose, croscarmellose sodium, magnesium stearate, colloidal silica (e.g., anhydrous colloidal silica) or a combination thereof), to provide a blend;

b) tableting the blend (e.g., using a tableting press) to provide a core tablet;

c) optionally, coating the core tablet with an anti-moisture barrier, to provide an anti-moisture coated tablet; and

d) coating the core tablet of step (b) or the anti-moisture coated tablet of step (c) with a delayed-release coating, to provide a delayed-release coated tablet.