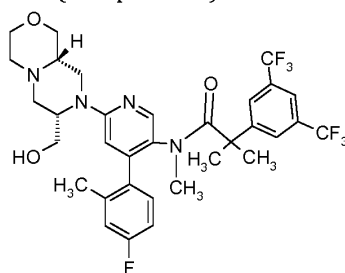


CLAIMS

1. A pharmaceutical formulation, comprising:
 (a) 2-[3,5-Bis(trifluoromethyl)phenyl]-N-{4-(4-fluoro-2-methylphenyl)-6-
 5 [(7S,9aS)-7-(hydroxymethyl)hexahydropyrazino[2,1-c][1,4]oxazin-8(1H)-yl]-3-pyridinyl}-
 N,2-dimethylpropanamide (Compound A):



(Compound A)

- or a pharmaceutically acceptable salt thereof; and
 (b) at least one solubilizer.
- 10 2. The pharmaceutical formulation of claim 1, wherein Compound A is in a crystalline form.
3. The pharmaceutical formulation of claims 1 or 2, wherein Compound A is in
 15 anhydrous crystalline Form 1.
4. The pharmaceutical formulation of any one of claims 1-3, further comprising an antioxidant.
- 20 5. The pharmaceutical formulation of any one of claims 1-4, further comprising an emulsifier.
6. The pharmaceutical formulation of any one of claims 1-5, further comprising one
 or more additional therapeutic agents.
- 25 7. The pharmaceutical formulation of any one of claims 1 or 4-6, being of a liquid oral formulation.
8. The pharmaceutical formulation of any one of claims 1-7, being of a soft gelatin
 30 capsule.
9. The pharmaceutical formulation of any one claims 1-8, wherein concentration of
 Compound A in the pharmaceutical formulation ranges from 0.8 % w/w to 15% w/w.
- 35 10. The pharmaceutical formulation of any one of claims 1-9, wherein the amount of
 Compound A in the pharmaceutical formulation ranges from 10 mg to 80 mg.

11. The pharmaceutical formulation of any one claims 1-10, wherein the solubilizer is selected from Caprylocaproyl polyoxyl-8 glycerides (Labrasol ALF), Glycerol Monocaprylocaprate (Capmul MCM), Polyoxyl 35 castor oil (Kolliphor EL), Polysorbate 80 (Tween 80), or mixtures thereof.
12. The pharmaceutical formulation of any one of claims 1-10, wherein the solubilizer is a mixture of Glycerol Monocaprylocaprate (Capmul MCM), Caprylocaproyl polyoxyl-8 glycerides (Labrasol ALF), and Polysorbate 80 (Tween 80), wherein the concentration of the Glycerol Monocaprylocaprate (Capmul MCM) ranges from 30% w/w to 40% w/w, the concentration of Caprylocaproyl polyoxyl-8 glycerides (Labrasol ALF) ranges from 9% w/w to 10% w/w, the concentration of the Polysorbate 80 (Tween 80) ranges from 9% w/w to 10% w/w.
13. The pharmaceutical formulation of any one claims 5-12, wherein the emulsifier is Glyceryl Monooleate (Peceol).
14. The pharmaceutical formulation of any one claims 4-13, wherein the antioxidant is selected from DL-Alpha tocopherol (Vitamin E), butylated hydroxytoluene (BHT), and butylated hydroxyanisole (BHA), and mixtures thereof.
15. The pharmaceutical formulation of claim 14, wherein the antioxidant is DL-Alpha tocopherol (Vitamin E) at a concentration ranging from 0.05% w/w to 1.5% w/w.
16. The pharmaceutical formulation of any one of claims 1-15, comprising Compound A, Glycerol Monocaprylocaprate (Capmul MCM), Polysorbate 80 (Tween 80), Glyceryl Monooleate (Peceol), and DL-alpha tocopherol (Vitamin E).
17. The pharmaceutical formulation of any one of claims 1-15, comprising Compound A, Glycerol Monocaprylocaprate (Capmul MCM), Caprylocaproyl polyoxyl-8 glycerides (Labrasol ALF), Polysorbate 80 (Tween 80), Glyceryl Monooleate (Peceol), and DL-alpha tocopherol (Vitamin E).
18. The pharmaceutical formulation of claim 17, comprising:
- (a) Compound A from about 1% w/w to about 10% w/w or from 5% w/w to 10% w/w;
 - (b1) Glycerol Monocaprylocaprate (MCM) presented at a concentration ranging from 30% w/w to 40% w/w;
 - (b2) Caprylocaproyl polyoxyl-8 glycerides (Labrasol ALF) presented at a concentration ranging from 7% w/w to 13% w/w;
 - (b3) Polysorbate 80 (Tween 80) presented at a concentration from 7% w/w to 13% w/w;
 - (c) Glyceryl Monooleate (Peceol) presented at a concentration ranging from about 33% w/w to 43% w/w; and
 - (d) DL-Alpha tocopherol (Vitamin E) presented at a concentration ranging from 0.05% w/w to 1.5% w/w or ranging from 0.5% w/v to 1.0% w/v.

19. The pharmaceutical formulation of any one of claims 1-18, for use in the treatment or prevention of a sex hormone dependent disease, or in the treatment or prevention of a condition, wherein the condition is a symptom associated with the perimenopause, the menopause, or the post menopause. selected from a pathological gain of excess body fat
5 and/or excess body weight, insomnia, sleep disturbances and night-time awakenings, anxiety and depression, urinary symptoms of urgency and dysuria; or wherein the condition is a symptom associated with andropause selected from a pathological gain of excess body fat and/or excess body weight, insomnia, sleep disturbances and night-time awakenings, anxiety and depression, urinary symptoms of urgency and dysuria.
- 10 20. The pharmaceutical formulation for use of claim 19, wherein the sex-hormone dependent disease is selected from endometriosis, uterine fibrosis, heavy menstrual bleeding, polycystic ovary syndrome (PCOS) and hot flushes.
- 15 21. The pharmaceutical formulation for use of claim 19, wherein the sex-hormone dependent disease is hot flushes.
22. Compound A or pharmaceutically acceptable salts thereof for use in the treatment or prevention of a condition, wherein the condition is a symptom of the perimenopause, the menopause, or the post menopause selected from a pathological gain of excess body fat
20 and/or excess body weight, insomnia, sleep disturbances and night-time awakenings, anxiety and depression, urinary symptoms of urgency and dysuria; or a symptom associated with the andropause selected from a pathological gain of excess body fat and/or excess body weight, insomnia, sleep disturbances, night-time awakenings, anxiety and depression,
25 urinary symptoms of urgency and dysuria.
23. A method for preparing the pharmaceutical formulations according to claims 1-18 by mixing Compound A or a pharmaceutically acceptable salts thereof with at least of one excipient.
- 30 24. The method of claim 23, wherein Compound A is in anhydrous crystalline Form1.
25. A method for producing a soft gelatin capsule comprising the steps of providing a capsule shell, mixing a formulation comprising Compound A or pharmaceutically acceptable
35 salts thereof and at least one excipient, and incorporating the formulation into the capsule shell.