WHAT IS CLAIMED IS:

1. A method for reducing frequency of urination in a subject, comprising:

administering to a subject in need thereof an effective amount of one or more analgesic agents and an effective amount of tadalafil.

2. The method of Claim 1, wherein said one or more analgesic agents are formulated for extended release and wherein said tadalafil is formulated for immediate release.

3. The method of Claim 1, wherein said one or more analgesic agents are formulated for delayed release and wherein said tadalafil is formulated for immediate release.

4. A method for reducing frequency of urination in a subject, comprising:

administering to a subject in need thereof a pharmaceutical composition comprising:

an active ingredient comprising one or more analgesic agents in an amount of 1-2000 mg per agent; and

an inhibitor of phosphodiesterase type 5 (PDE 5 inhibitor),

wherein said one or more analgesic agents are selected from the group consisting of aspirin, ibuprofen, naproxen, naproxen sodium, indomethacin, nabumetone, and acetaminophen.

5. The method of Claim 4, wherein said pharmaceutical composition is coated with an enteric coating.

6. The method of Claim 4, wherein said pharmaceutical composition is formulated for extended release, characterized by a two-phase release profile in which 20-60% of said active ingredient is released within two hours of administration and remainder of said active ingredient is released continuously over a period of 2-12 hours.

7. The method of Claim 6, wherein said pharmaceutical composition is coated with an enteric coating.

8. The method of Claim 4, wherein said one or more analgesic agents comprises acetaminophen.

9. The method of Claim 4, wherein said active ingredient further comprises an additional agent selected from the group consisting of antimuscarinic agents, antidiuretics, spasmolytics and zolpidem.

10. The method of Claim 4, wherein said PDE 5 inhibitor is tadalafil.

11. A method for reducing the frequency of urination in a subject, comprising:

administering to a subject in need thereof a pharmaceutical composition comprising:

a first active ingredient comprising one or more analgesic agents and tadalafil; and

a second active ingredient comprising one or more agents selected from the group consisting of analgesic agents, antimuscarinic agents, antidiuretics, spasmolytics, PDE 5 inhibitors and zolpidem,

wherein said first active ingredient is formulated for immediate release and wherein said second active ingredient is formulated for extended release.

12. The method of Claim 11, wherein said pharmaceutical composition is further coated with an enteric coating.

13. The method of Claim 11, wherein said first active ingredient comprises acetaminophen.

14. The method of Claim 11, wherein said first active ingredient further comprises an antimuscarinic agent, an antidiuretic, a spasmolytic or zolpidem.

15. A pharmaceutical composition, comprising:

one or more analgesic agents;

a PDE 5 inhibitor; and

a pharmaceutically acceptable carrier.

16. The pharmaceutical composition of Claim 15, wherein said one or more analgesic agents are formulated for extended-release and wherein said PDE 5 inhibitor is formulated for immediate-release.

17. The pharmaceutical composition of Claim 15, wherein said one or more analgesic agents are formulated for delayed-release and wherein said PDE 5 inhibitor is formulated for immediate-release.

18. The pharmaceutical composition of Claim 15, wherein said one or more analgesic agents and said PDE 5 inhibitor are formulated for extended release over a period of 2-12 hours.

19. The pharmaceutical composition of Claim 15, wherein said PDE 5 inhibitor and 20-60% of each of said one or more analgesic agents are formulated for immediate release, and wherein remainder of each of said one or more analgesic agents is formulated for extended release.

20. The pharmaceutical composition of Claim 19, wherein said pharmaceutical composition is further coated with an enteric coating.

AMENDED CLAIMS
received by the International Bureau on 31 December 2013 (31.12.2013)

1. Use of a pharmaceutical composition for reducing frequency of urination in a subject in need thereof, said pharmaceutical composition comprising:

an effective amount of one or more analgesic agents and an effective amount of tadalafil.

2. The use of Claim 1, wherein said one or more analgesic agents are formulated for extended release and wherein said tadalafil is formulated for immediate release.

3. The use of Claim 1, wherein said one or more analgesic agents are formulated for delayed release and wherein said tadalafil is formulated for immediate release.

4. Use of a pharmaceutical composition for reducing frequency of urination in a subject in need thereof, said pharmaceutical composition comprising:

an active ingredient comprising one or more analgesic agents in an amount of 1-2000 mg per agent; and

an inhibitor of phosphodiesterase type 5 (PDE 5 inhibitor),

wherein said one or more analgesic agents are selected from the group consisting of aspirin, ibuprofen, naproxen, naproxen sodium, indomethacin, nabumetone, and acetaminophen.

5. The use of Claim 4, wherein said pharmaceutical composition is coated with an enteric coating.

6. The use of Claim 4, wherein said pharmaceutical composition is formulated for extended release, characterized by a two-phase release profile in which 20-60% of said active ingredient is released within two hours of administration and remainder of said active ingredient is released continuously over a period of 2-12 hours.

7. The use of Claim 6, wherein said pharmaceutical composition is coated with an enteric coating.

8. The use of Claim 4, wherein said one or more analgesic agents comprises acetaminophen.

9. The use of Claim 4, wherein said active ingredient further comprises an additional agent selected from the group consisting of antimuscarinic agents, antidiuretics, spasmolytics and zolpidem.

10. The use of Claim 4, wherein said PDE 5 inhibitor is tadalafil.

11. Use of a pharmaceutical composition for reducing frequency of urination in a subject in need thereof, said pharmaceutical composition comprising:

a first active ingredient comprising one or more analgesic agents and tadalafil; and

a second active ingredient comprising one or more agents selected from the group consisting of analgesic agents, antimuscarinic agents, antidiuretics, spasmolytics, PDE 5 inhibitors and zolpidem,

wherein said first active ingredient is formulated for immediate release and wherein said second active ingredient is formulated for extended release.

12. The use of Claim 11, wherein said pharmaceutical composition is further coated with an enteric coating.

13. The use of Claim 11, wherein said first active ingredient comprises acetaminophen.

14. The use of Claim 11, wherein said first active ingredient further comprises an antimuscarinic agent, an antidiuretic, a spasmolytic or zolpidem.

15. A pharmaceutical composition for reducing frequency of urination, comprising:

one or more analgesic agents;

a PDE 5 inhibitor; and

a pharmaceutically acceptable carrier,

wherein said pharmaceutical composition is formulated in a manner selected from the group consisting of: a) said one or more analgesic agents are formulated for extended-release and wherein said PDE 5 inhibitor is formulated for immediate-release, b) said one or more analgesic agents are formulated for delayed-release and wherein said PDE 5 inhibitor is formulated for immediate-release, c) said one or more analgesic agents and said PDE 5 inhibitor are formulated for extended release over a period of 2-12 hours, and d) said PDE 5 inhibitor and 20-60% of each of said one or more analgesic agents are formulated for immediate release, and wherein remainder of each of said one or more analgesic agents is formulated for extended release.

16. The pharmaceutical composition of Claim 15, wherein said one or more analgesic agents are formulated for extended-release and wherein said PDE 5 inhibitor is formulated for immediate-release.

17. The pharmaceutical composition of Claim 15, wherein said one or more analgesic agents are formulated for delayed-release and wherein said PDE 5 inhibitor is formulated for immediate-release.

18. The pharmaceutical composition of Claim 15, wherein said one or more analgesic agents and said PDE 5 inhibitor are formulated for extended release over a period of 2-12 hours.

19. The pharmaceutical composition of Claim 15, wherein said PDE 5 inhibitor and 20-60% of each of said one or more analgesic agents are formulated for immediate release, and wherein remainder of each of said one or more analgesic agents is formulated for extended release.

20. The pharmaceutical composition of Claim 15, wherein said pharmaceutical composition is further coated with an enteric coating.

WHAT IS CLAIMED IS:

1. The use of a pharmaceutical composition comprising an effective amount of one or more analgesic agents and an effective amount of tadalafil, in the manufacture of a medicament for reducing frequency of urination

2. The use of the pharmaceutical composition of Claim 1, wherein said pharmaceutical composition is formulated for immediate release, delayed release, extended release or combinations thereof.

3. The use of the pharmaceutical composition of Claim 1, wherein said one or more analgesic agents are formulated for extended release and wherein said tadalafil is formulated for immediate release.

4. The use of the pharmaceutical composition of Claim 1, wherein said one or more analgesic agents are formulated for delayed release and wherein said tadalafil is formulated for immediate release.

5. The use of the pharmaceutical composition of any one of Claims 1-4, wherein said one or more analgesic agents comprises acetaminophen.

6. The use of the pharmaceutical composition of Claim 5, wherein said one or more analgesic agents comprises acetaminophenin in an amount of 1-2000 mg.

7. The use of the pharmaceutical composition of any one of Claims 1-6, wherein said pharmaceutical composition further comprises an additional agent selected from the group consisting of antimuscarinic agents, antidiuretics, spasmolytics and zolpidem.

8. The use of a pharmaceutical composition comprising:

an active ingredient comprising:

one or more analgesic agents in an amount of 1-2000 mg per agent; and

an inhibitor of phosphodiesterase type 5 (PDE 5 inhibitor),

wherein said one or more analgesic agents are selected from the group consisting of aspirin, ibuprofen, naproxen, naproxen sodium, indomethacin,

nabumetone, and acetaminophen, in the manufacture of a medicament for reducing frequency of urination.

9. The use of the pharmaceutical composition of Claim 8, wherein said pharmaceutical composition is formulated for immediate release, delayed release, extended release or combinations thereof.

10. The use of the pharmaceutical composition of Claim 8, wherein said pharmaceutical composition is formulated for delayed release.

11. The use of the pharmaceutical composition of Claim 8, wherein said pharmaceutical composition is formulated for extended release.

12. The use of the pharmaceutical composition of one of Claims 8-11, wherein said one or more analgesic agents comprises acetaminophen.

13. The use of the pharmaceutical composition of any one of Claims 8-12, wherein said active ingredient further comprises an additional agent selected from the group consisting of antimuscarinic agents, antidiuretics, spasmolytics and zolpidem.

14. The use of the pharmaceutical composition of any one of Claims 8-13, wherein said PDE 5 inhibitor is tadalafil.

15. A pharmaceutical composition for reducing frequency of urination, comprising:

one or more analgesic agents;

a PDE 5 inhibitor; and

a pharmaceutically acceptable carrier,

wherein said pharmaceutical composition is formulated in a manner selected from the group consisting of: a) said one or more analgesic agents are formulated for extended-release and wherein said PDE 5 inhibitor is formulated for immediate-release, b) said one or more analgesic agents are formulated for delayed-release and wherein said PDE 5 inhibitor is formulated for immediate-release, c) said one or more analgesic agents and said PDE 5 inhibitor are formulated for extended release over a period of 2-12 hours, and d) said PDE 5 inhibitor and 20-60% of each of said one or more analgesic agents are formulated for

immediate release, and wherein remainder of each of said one or more analgesic agents is formulated for extended release.

16. The pharmaceutical composition of Claim 15, wherein said one or more analgesic agents are formulated for extended-release and wherein said PDE 5 inhibitor is formulated for immediate-release.

17. The pharmaceutical composition of Claim 15, wherein said one or more analgesic agents are formulated for delayed-release and wherein said PDE 5 inhibitor is formulated for immediate-release.

18. The pharmaceutical composition of Claim 15, wherein said one or more analgesic agents and said PDE 5 inhibitor are formulated for extended release over a period of 2-12 hours.

19. The pharmaceutical composition of Claim 15, wherein said PDE 5 inhibitor and 20-60% of each of said one or more analgesic agents are formulated for immediate release, and wherein remainder of each of said one or more analgesic agents is formulated for extended release.

20. The pharmaceutical composition of Claim 15, wherein said pharmaceutical composition is further coated with an enteric coating.

21. The use of the pharmaceutical composition of any one of Claims 1, wherein said pharmaceutical composition is in a liquid or solid formulation.

22. The pharmaceutical composition of Claim 15, wherein said pharmaceutical composition is in a liquid or solid formulation.