Claims

1. The use of a pharmaceutical composition comprising an effective amount of acetaminophen and/or ibuprofen and an effective amount of tadalafil, in the manufacture of a medicament for reducing frequency of urination in a subject with nocturia.

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 acetaminophen 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, wherein said antimuscarinic agents are selected from the group consisting of oxybutynin, solifenacin, darifenacin, fesoterodine, tolterodine, trospium, atropine; and wherein said antidiuretics are selected from the group consisting of antidiuretic hormone (ADH), angiotensin II, aldosterone, vasopressin, vasopressin analogs, desmopressin, argipressin, lypressin, felypressin, oraipressin, terlipressin, atrial natriuretic peptide (ANP) and C-type natriuretic peptide (CNP) receptor (NPR1 , NPR2, NPR3) antagonists, HS-142-1 , isatin, somatostatin type 2 receptor antagonists, somatostatin; and further wherein said spasmolytics are selected from the group consisting of carisoprodol, benzodiazepines, baclofen, cyclobenzaprine, metaxalone, methocarbamol, clonidine, clonidine analog, and dantrolene.

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 in a subject with nocturia, and wherein said PDE 5 inhibitor is selected from the group consisting of tadalafil, sildenafil and vardenafil.

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, wherein said antimuscarinic agents are selected from the group consisting of oxybutynin, solifenacin, darifenacin, fesoterodine, tolterodine, trospium, atropine; and wherein said antidiuretics are selected from the group consisting of antidiuretic hormone (ADH), angiotensin II, aldosterone, vasopressin, vasopressin analogs, desmopressin, argipressin, lypressin, felypressin, oraipressin, terlipressin, atrial natriuretic peptide (ANP) and C-type natriuretic peptide (CNP) receptor (NPR1 , NPR2, NPR3) antagonists, HS-142-1 , isatin, somatostatin type 2 receptor antagonists, somatostatin; and further wherein said spasmolytics are selected from the group consisting of carisoprodol, benzodiazepines, baclofen, cyclobenzaprine, metaxalone, methocarbamol, clonidine, clonidine analog, and dantrolene.

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 use in reducing frequency of urination in a subject with nocturia, 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, wherein said analgesic agents are selected from the group consisting of acetaminophen, ibuprofen, aspirin, naproxen sodium, indomethacin, and nabumetone; and wherein said PDE 5 inhibitor is selected from the group consisting of tadalafil, sildenafil and vardenafil.

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 15-20 in the manufacture of a medicament for reducing frequency of urination in a subject with nocturia, 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.