

Claims

1. A composition for the treatment of chronic vulval or perineal pain or a symptom or condition associated therewith, the composition comprising an estrogen and a tricyclic antidepressant, wherein the composition is formulated for topical, transdermal or transmucosal administration.
2. A composition according to claim 1, wherein the estrogen is a natural or synthetic estrogen.
3. A composition according to claim 1 or 2, wherein the estrogen is selected from the group consisting of estriol, estrone, 17 beta-estradiol, estradiol, estradiol benzoate, estradiol 17 beta-cypionate, ethinyl estradiol, mestranol, moxestrol, mytatrienediol, polyestradiol phosphate, quinestradiol, quinestrol, and any combination thereof.
4. A composition according to any one of claims 1 to 3, wherein the estrogen displays weak estrogenic activity.
5. A composition according to claim 4, wherein the estrogen is estriol.
6. A composition according to any one of claims 1 to 5, wherein the tricyclic antidepressant is selected from amitriptyline, nortriptyline and desipramine.
7. A composition according to any one of claims 1 to 6, wherein the tricyclic antidepressant is amitriptyline.
8. A composition according to any one of claims 1 to 7, wherein the composition is a topical composition.
9. A composition according to any one of claims 1 to 8, wherein the composition is in the form of a gel.

10. A composition according to any one of claims 1 to 9, wherein the composition is produced using a mixture of an organic phase and an aqueous phase.
11. A composition according to claim 10, wherein the organic phase comprises the estrogen, optionally the estriol, and the aqueous phase comprises the tricyclic antidepressant, optionally amitriptyline.
12. A composition according to any one of claims 1 to 11, wherein the condition is vulvodynia or pudendal neuralgia, or a symptom associated therewith.
13. A composition according to any one of claims 1 to 12, wherein the condition is selected from vulval vestibulitis, localized provoked vestibulodynia (LPV), dysesthetic vulvodynia, vulvar dermatoses or cyclic vulvovaginitis.
14. A composition according to any one of claims 1 to 13, wherein the condition or symptom associated with chronic vulval or perineal pain comprises urethritis, urinary frequency or urgency, or faecal frequency or urgency.
15. A topical composition for the treatment of chronic vulval or perineal pain or a symptom or condition associated therewith, the composition comprising estriol and amitriptyline.
16. A method for the treatment of chronic vulval or perineal pain or a symptom or condition associated therewith, the method comprising topically, transdermally or transmucosally administering to a female subject in need thereof a composition according to any one of claims 1 to 15.
17. A method according to claim 16, wherein the condition is vulvodynia or pudendal neuralgia, or a symptom associated therewith.
18. A method according to claim 16 or 17, wherein the condition is selected from vulval vestibulitis, localized provoked vestibulodynia (LPV), dysesthetic vulvodynia, vulvar dermatoses or cyclic vulvovaginitis.

19. A method according to any one of claims 16 to 18, wherein the condition or symptom associated with chronic vulval or perineal pain comprises urethritis, urinary frequency or urgency, or faecal frequency or urgency.

20. A method according to any one of claims 16 to 19, wherein the composition is a topical composition.

21. A method according to any one of claims 16 to 20, wherein the composition is a gel.

22. A method for the treatment of chronic vulval or perineal pain or a symptom or condition associated therewith, the method comprising topically administering to a female subject in need thereof a composition comprising estriol and amitriptyline.

23. Use of an estrogen and a tricyclic antidepressant for the manufacture of a composition for the treatment of chronic vulval or perineal pain or a symptom or condition associated therewith, wherein the composition is formulated for topical, transdermal or transmucosal administration.

24. Use of estriol and amitriptyline for the manufacture of a composition for the treatment of chronic vulval or perineal pain or a symptom or condition associated therewith, wherein the composition is formulated for topical administration.