CLAIMS

1. A composition comprising at least about 9% by weight terbinafine or a pharmaceutically acceptable salt thereof, hydroxypropyl chitosan, a lower alkanol and water for use in treating onychomycosis in a patient, wherein said composition is applied to the affected areas of said patient once weekly.
2. A composition for use according to claim 1, wherein a loading dose treatment period precedes the weekly application.
3. A composition for use according to claim 2, wherein the loading dose treatment period comprises daily application for a period of time from two weeks to up to two months.
4. A composition for use according to claim 3, wherein the loading dose treatment period comprises daily application for one month.
5. A composition for use according to claim 1, wherein terbinafine or a pharmaceutically acceptable salt thereof is present in an amount from 9.5% to 10.5% by weight.
6. A composition for use according to claim 1, wherein said lower alkanol is ethanol.
7. A composition for use according to claim 1, wherein said pharmaceutically acceptable salt is terbinafine HCl.
8. A composition for use in treating onychomycosis essentially consisting of:
   a) terbinafine and/or at least a pharmaceutically acceptable salt thereof in an amount of from 9 to 11% by weight of the composition,

b) hydroxypropyl chitosan in an amount of from 0.1 to 0.6% by weight of the composition,

c) water in an amount of from 10.0 to 40.0% by weight of the composition,

d) at least a lower alkanol in an amount of from 60 to 80% by weight of the composition.

9. A composition for use according to claim 8, wherein component a) is terbinafine HCl.

10. A composition for use according to claim 8, wherein component b) is present in an amount from 0.2 to 0.4% by weight of the composition.

11. A composition for use according to claim 8, wherein component c) is present in an amount from 18 to 30% by weight of the composition.

12. A composition for use according to claim 8, wherein component d) is selected from ethanol, propanol, isopropanol, butanol and mixtures thereof.

13. A composition for use according to claim 12, wherein component d) is ethanol.

14. A composition for use according to claim 8, wherein the composition consists of a) 9.5 to 10.5% by weight terbinafine HCl, b) 0.2 to 0.4% by weight hydroxypropyl chitosan, c) 18 to 30% by weight purified water and d) 65 to 75% by weight ethanol

15. A composition for use according to claim 14, wherein the composition consists of a) about 10% by weight terbinafine HCl, b) about 0.3% by weight hydroxypropyl chitosan, c) about 19.7% by weight purified water and d) about 70% by weight ethanol.

16. A composition for use according to claim 8, wherein the composition is in the form of a nail lacquer.

17. A composition for use according to claim 8, wherein the composition is applied once weekly.
18. A composition for use according to claim 8, wherein the composition is applied once daily for the first month, then once weekly until the end of a treatment.
19. A composition essentially consisting of:
    a) terbinafine and/or at least a pharmaceutically acceptable salt thereof in an amount from 9 to 11% by weight of the composition,
    b) hydroxypropyl chitosan in an amount from 0.1 to 0.6% by weight of the composition,
    c) water in an amount from 10.0 to 40.0% by weight of the composition,
    d) at least a lower alkanol in an amount from 60 to 80% by weight of the composition.
20. The composition of claim 19, wherein component a) is terbinafine HCl.
21. The composition of claim 19, wherein component b) is present in an amount from 0.2 to 0.4% by weight of the composition.
22. The composition of claim 19, wherein component c) is present in an amount from 18 to 30% by weight of the composition.
23. The composition of claim 19, wherein component d) is selected from ethanol, propanol, isopropanol, butanol and mixtures thereof.
24. The composition of claim 23, wherein component d) is ethanol.
25. The composition of claim 19, which consists of a) 9.5 to 10.5% by weight terbinafine HCl, b) 0.2 to 0.4% by

weight hydroxypropyl chitosan, c) 18 to 30% by weight purified water and d) 65 to 75% by weight ethanol.

26. The composition of claim 25, which consists of a) about 10% by weight terbinafine HCl, b) about 0.3% by weight hydroxypropyl chitosan, c) about 19.7% by weight purified water and d) about 70% by weight ethanol.

27. The composition of claim 19, wherein it is in the form of a nail lacquer.

CLAIMS

1. The use of a composition comprising at least about 9% by weight terbinafine or a pharmaceutically acceptable salt thereof, hydroxypropyl chitosan, a lower alkanol and water in the manufacture of a medicament for the treatment of onychomycosis, wherein said medicament is to be administered topically once weekly.
2. The use according to claim 1, wherein a loading dose treatment period precedes the weekly application.
3. The use according to claim 2, wherein the loading dose treatment period comprises daily application for a period of time from two weeks to up to two months.
4. The use according to claim 3, wherein the loading dose treatment period comprises daily application for one month.
5. The use according to claim 1, wherein terbinafine or a pharmaceutically acceptable salt thereof is present in an amount from 9.5% to 10.5% by weight.
6. The use according to claim 1, wherein said lower alkanol is ethanol.
7. The use according to claim 1, wherein said pharmaceutically acceptable salt is terbinafine HCl.
8. The use of a composition comprising:
   a) terbinafine and/or at least a pharmaceutically acceptable salt thereof in an amount of from 9 to 11% by weight of the composition,
   b) hydroxypropyl chitosan in an amount of from 0.1 to 0.6% by weight of the composition,
   c) water in an amount of from 10.0 to 40.0% by weight of the composition,

d) at least a lower alkanol in an amount of from 60 to 80% by weight of the composition,

in the manufacture of a medicament for the treatment of onychomycosis,

with the proviso that plasticizers and/or penetration enhancers are excluded from the composition.

9. The use according to claim 8, wherein component a) is terbinafine HCl.
10. The use according to claim 8, wherein component b) is present in an amount from 0.2 to 0.4% by weight of the composition.
11. The use according to claim 8, wherein component c) is present in an amount from 18 to 30% by weight of the composition.
12. The use according to claim 8, wherein component d) is selected from ethanol, propanol, isopropanol, butanol and mixtures thereof.
13. The use according to claim 12, wherein component d) is ethanol.
14. The use according to claim 8, wherein the composition consists of a) 9.5 to 10.5% by weight terbinafine HCl, b) 0.2 to 0.4% by weight hydroxypropyl chitosan, c) 18 to 30% by weight purified water and d) 65 to 75% by weight ethanol
15. The use according to claim 14, wherein the composition consists of a) about 10% by weight terbinafine HCl, b) about 0.3% by weight hydroxypropyl chitosan, c) about 19.7% by weight purified water and d) about 70% by weight ethanol.
16. The use according to claim 8, wherein the composition is in the form of a nail lacquer.

17. The use according to claim 8, wherein the composition is applied once weekly.
18. The use according to claim 8, wherein the composition is applied once daily for the first month, then once weekly until the end of a treatment.
19. A composition comprising:
    a) terbinafine and/or at least a pharmaceutically acceptable salt thereof in an amount from 9 to 11% by weight of the composition,
    b) hydroxypropyl chitosan in an amount from 0.1 to 0.6% by weight of the composition,
    c) water in an amount from 10.0 to 40.0% by weight of the composition,
    d) at least a lower alkanol in an amount from 60 to 80% by weight of the composition,

    with the proviso that plasticizers and/or penetration enhancers are excluded from the composition.
20. The composition of claim 19, wherein component a) is terbinafine HCl.
21. The composition of claim 19, wherein component b) is present in an amount from 0.2 to 0.4% by weight of the composition.
22. The composition of claim 19, wherein component c) is present in an amount from 18 to 30% by weight of the composition.
23. The composition of claim 19, wherein component d) is selected from ethanol, propanol, isopropanol, butanol and mixtures thereof.
24. The composition of claim 23, wherein component d) is ethanol.

25. The composition of claim 19, which consists of a) 9.5 to 10.5% by weight terbinafine HCl, b) 0.2 to 0.4% by weight hydroxypropyl chitosan, c) 18 to 30% by weight purified water and d) 65 to 75% by weight ethanol.
26. The composition of claim 25, which consists of a) about 10% by weight terbinafine HCl, b) about 0.3% by weight hydroxypropyl chitosan, c) about 19.7% by weight purified water and d) about 70% by weight ethanol.
27. The composition of claim 19, wherein it is in the form of a nail lacquer.