Claims

1. Use of 0.1 % (w/v) cyclosporine dissolved in 1-(perfluorobutyl)pentane and up to 1.0% (w/w) ethanol in the manufacture of an ophthalmic composition for treating keratoconjunctivitis sicca (dry eye disease) in a patient, wherein the patient has a total ocular surface disease index (OSDI) score of equal or greater than 55 and wherein the ophthalmic composition is to be topically administered to an eye of a patient twice per day per eye as a single drop having volume of 8 to 10 µl.

2. Use of 0.1 % (w/v) cyclosporine dissolved in 1-(perfluorobutyl)pentane and up to 1.0 % (w/w) ethanol in the manufacture of an ophthalmic composition for treating and/or ameliorating the symptoms associated with keratoconjunctivitis sicca (dry eye disease), wherein the symptoms are dryness and blurred vision, wherein the patient has a total ocular surface disease index (OSDI) score of equal or greater than 55 and wherein the ophthalmic composition is to be topically administered to an eye of a patient twice per day per eye as a single drop having a volume of 8 to 10 µl.

3. The use according to claim 2, wherein the dryness (severity of dryness), and the blurred vision, are determined on a visual analog scale (VAS) on a scale of 0% to 100%, wherein the scale of 0% to 100% is the percentage level of discomfort experienced by a patient.

4. The use according to claim 1, wherein the patient has at least one eye, or both eyes with any one or combination of i. a central corneal fluorescein staining (NEI scale) score of 2 or higher, ii. an inferior corneal fluorescein staining (NEI scale) score of 2 or higher, iii. a total corneal fluorescein staining (NEI scale) score of 11 or higher.

5. The use according to any one of the preceding claims, wherein the ophthalmic composition consists of 0.1 % (w/v) cyclosporine, 1-(perfluorobutyl)pentane and up to 1.0 % (w/w) ethanol, or wherein the composition consists of 0.1 % (w/v) cyclosporine, 1-(perfluorobutyl)pentane and 1.0 % (w/w) ethanol.

6. The use according to any one of the preceding claims, wherein the ophthalmic composition is used to treat and reduce ocular surface damage of the cornea, and

wherein the subject has a total corneal fluorescein staining score of at least equal to, or greater than 10, or greater than 11.

7. The use according to any one of the preceding claims, wherein the ophthalmic composition is used to reduce corneal and/or conjunctival damage, wherein the subject has a central corneal fluorescein staining score of at least equal to, or greater than 2 as based on the NEI grading scale of 0-3; and optionally, a total lissamine green conjunctival staining score (sum of temporal and nasal regions) based on the Oxford scale, of at least equal to, or greater than 2.

8. The use according to any one of the preceding claims, wherein ophthalmic composition is effective in reducing ocular surface damage.

9. The use according to claim 8, wherein the ocular surface damage is selected from ocular surface damage of the central corneal region and ocular surface damage of the inferior corneal region.

10. The use according to claim 8 or 9, wherein the ophthalmic composition is effective in reducing the total corneal fluorescein staining score (sum of inferior, superior, central, nasal, and temporal staining scores; NEI scale) by an integer at least 3 grades within a period of at least 8 weeks, or 4 weeks.

11. The use according to any of the preceding claims, wherein the patient has at least one eye with any one or combination of criteria selected from the group consisting of:

    - a total corneal fluorescein staining value in the range of 10 to 15, preferably 10 to 13 (NEI scale);

    - a central corneal fluorescein staining value in the range of 1 to 3 (NEI scale); preferably 2 to 3 (NEI scale)

    - a total lissamine green conjunctival staining score in the range of 2 to 6, preferably 3 to 5;

    -a total OSDI score in the range of 25 to 64, preferably 30 to 64;

    - an unanesthetized Schirmer's test score in the range of 2 to 8 mm.

12. The use of any of the preceding claims, wherein the patient has an unanesthetized Schirmer's Test score in at least one eye in the range of 3 to 7 mm, preferably in the range of 4 to 6 mm, more preferably of about 5 mm.

13. The use according to any one of the preceding claims, wherein the patient has a history of keratoconjunctivitis sicca (dry eye disease) in one or both eyes for at least six months, or wherein the patient was unresponsive or insufficiently responsive to previous treatment for keratoconjunctivitis sicca (dry eye disease).

14. The use according to any one of the preceding claims, wherein the dry eye disease is evaporative dry eye disease.

15. The use according to any one of claims 1 to 13, wherein the dry eye disease is aqueous-deficient dry eye disease.

16. The use according to claim 13, wherein the patient was unresponsive or insufficiently responsive to a previous treatment for keratoconjunctivitis sicca (dry eye disease), and wherein said previous treatment method is selected from topical aqueous immunosuppressant administration, topical corticosteroid administration, and topical aqueous artificial tears administration.