Claims

1. A composition, comprising:
0.01 mg/mL to 30 mg/mL anakinra;
buffer, selected from HEPES and a mixture of HEPES and sodium citrate; and
optionally at least one osmolyte.

2. The composition according to claim 1, comprising at least one osmolyte.

3. The composition according to claim 1, wherein said buffer is HEPES buffer.

4. The composition according to any one of claims 1 to 3, wherein said buffer stabilizes the pH of the composition at a pH of from 6 to 7.

5. The composition according to any one of claims 1 to 4, comprising 2 mg/mL to 30 mg/mL anakinra.

6. The composition according to any one of claims 1 to 5, wherein said at least one osmolyte is selected from taurine and hydroxyproline.

7. The composition according according to any one of claims 1 to 5, wherein said at least one osmolyte is taurine.

8. The composition according to any one of claims 1 to 5, wherein said at least one osmolyte is hydroxyproline.

9. The composition according to any one of claims 1 to 8, further comprising one or more of a chelating agent, a surfactant and a tonicity regulator.

10. The composition according to claim 9, wherein said chelating agent is EDTA, said surfactant is polysorbate 80 and said tonicity regulator is

NaCl.

11. The composition according to any one of claims 1 to 10, wherein the buffer stabilizes the pH of the composition at about 6.5.

12. The composition according to any one of claims 1 to 11, wherein the concentration of said osmolyte is adjusted to provide an isotonic composition.

13. The composition according to claim 12, wherein said composition has an osmolality of from 280 to 320 mOsmol/kg.

14. The composition according to any one of claims 1 to 11, wherein the concentration of said osmolyte is adjusted to provide a hypotonic composition.

15. The composition according to claim 14, wherein said composition has an osmolality of from 150 to 280 mOsmol/kg.

16. The composition according to claim 1, comprising
- 2 mg/mL to 25 mg/mL anakinra;
- 5 mM to 50 mM HEPES buffer, wherein said buffer stabilizes the pH of the composition at pH from 6 to 7; and
- 1 mg/mL to 100 mg/mL of an osmolyte selected from taurine and hydroxyproline.

17. The composition according to claim 1, comprising
- 2 mg/mL to 25 mg/mL anakinra;
- 5 mM to 50 mM HEPES buffer, wherein said buffer stabilizes the pH of the composition at pH from 6 to 7;
- 1 mg/mL to 100 mg/mL of an osmolyte selected from taurine, proline, hydroxyproline, mannitol and methionine;
- 0.05 mM to 1 mM EDTA;
- 0.01 % to 1 % polysorbate 80; and

- 0.1 mg/mL to 5 mg/mL NaCl.

18. The composition according to claim 15 or 16, wherein said buffer is 10 mM HEPES buffer, which stabilizes the pH of the composition at about 6.5.

19. The composition according to any one of claims 1 to 18, wherein said at least one osmolyte represents 15 mg/mL to 40 mg/mL taurine

20. The composition according to any one of claims 1 to 18, wherein said at least one osmolyte represents 20 mg/mL to 40 mg/mL taurine.

21. The composition according to any one of claims 1 to 18, wherein said at least one osmolyte represents 20 mg/mL to 40 mg/mL hydroxyproline.

22. The composition according to any one of claims 1 to 3, comprising
- 5 mg/mL to 25 mg/mL anakinra;
- 10 mM HEPES buffer, which stabilizes the pH of the composition at about 6.5; and
- about 30 mg/mL taurine.

23. The composition according to any one of claims 1 to 3, comprising
- 5 mg/mL to 25 mg/mL anakinra;
- 10 mM HEPES buffer, which stabilizes the pH of the composition at about 6.5;
- 0.5 mM EDTA;
- 0.1 % Polysorbate 80;
- 1 mg/mL to 1.5 mg/mL NaCl; and
- about 30 mg/mL taurine.

24. The composition according to claim 22 or 23, comprising from about 15 mg/mL to about 25 mg/mL anakinra.

25. The composition according to claim 1, comprising

- 2 mg/mL to 25 mg/mL anakinra;
- 10 mM – 50 mM HEPES buffer; and
- 15 mg/mL - 25 mg/mL taurine.

26. The composition according to claim 1, comprising
    - 2 mg/mL to 25 mg/mL anakinra;
    - 10 mM – 50 mM HEPES buffer; and
    - 15 mg/mL - 25 mg/mL hydroxyproline.

27. The composition according to any one of claims 1 to 26, wherein said composition is administered topically.

28. The composition according to claim 27, wherein said composition is administered topically to the eye.

29. The composition according to one of claims 1 to 26, wherein the composition is stored in a single or multi dose container.

30. The composition according to any one of claims 1 to 26, for use in the treatment of an ophthalmic disorder.

31. The composition according to any one of claims 1 to 26, for use in the treatment of an inflammatory ocular disorder.

32. The composition according to any one of claims 1 to 26, for use in the treatment of an ophthalmic IL-1 related disorder.

33. The composition according to any one of claims 1 to 26, for use in the treatment of primary or secondary Sjögren’s syndrome, Non-Sjögren's syndrome; dry eye disorder, keratitis sicca, sicca syndrome, xerophthalmia, tear film disorder, decreased tear production, aqueous tear deficiency, dry eye associated with graft-versus-host disease, Meibomian gland dysfunction, corneal ocular surface inflammatory

conditions, corneal neovascularization, keratitis, corneal wound healing, corneal transplantation/keratoplasty, keratoprosthesis surgery, lamellar transplantation, selective endothelial transplantation, conjunctival scarring disorders, allergic conjunctivitis, pemphigoid syndrome, Stevens-Johnson syndrome, sympathetic ophthalmia, Vogt-Koyanagi Harada (VKH) syndrome, birdshot retinochoriodopathy, ocular cicatricial pemphigoid, Fuch's heterochronic iridocyclitis, diabetic retinopathy, diabetic macular edema, thyroid eye disease, ectropion/entropion, contact lens allergy and dry eye disease.

34. The composition according to any one of claims 1 to 26, for use in the treatment of allergic conjunctivitis.

35. A drug delivery device comprising a composition according to any one of claims 1 to 26.

36. The device of claim 35, selected from a blow fill seal container, a single use container and multi use container.