CLAIMS

1. Use of an eye drop formulation in the manufacture of a topical medicament for use in treating diabetic macular edema in a human subject in need thereof, which includes

   (i) an induction phase of the eye drop formulation at a dosing of 6 drops a day for a period of 6 weeks, followed by,

   (ii) a maintenance phase of the eye drop formulation at a dosing of 3 drops a day;

   wherein said eye drop formulation comprises

   - 1.5% of dexamethasone;
   - 5 to 25% of γ-cyclodextrin;
   - 0.1% to 5% of poloxamer; and
   - water;

   wherein the % are % by weight based on the volume of the composition;

   and wherein said eye drop formulation comprises a microsuspension including complex aggregates of dexamethasone and γ-cyclodextrin.

2. The use of Claim 1, wherein the maintenance phase comprises a dosing of 3 drops a day, as long as necessary for the subject.

3. The use of Claim 1, wherein the maintenance phase comprises a dosing of 3 drops a day for a period of at least 46 weeks.

4. The use of any one of Claims 1-3, wherein the eye drop formulation comprises an amount of gamma-cyclodextrin from 12 to 16 %, by weight of γ-cyclodextrin based on the volume of the composition.

5. The eye drop formulation for use of any one of Claims 1-3, wherein the eye drop formulation comprises an amount of 2 to 3 % of poloxamer by weight of based on the volume of the composition.

6. The use of any one of Claims 1-5, wherein said eye drop formulation comprises or essentially consists of:

- 1.5% of dexamethasone;
- 12 to 16 % of γ-cyclodextrin;
- 2 to 2.7 % of poloxamer;
- 0 to 0.1% of chelating agent;
- 0 to 1% of electrolyte;
- 0% to 0.6% of an additive to prevent the oxidation of the dexamethasone, and
- water;

and wherein the pH is between 4.7 and 6.0,

wherein the % are % by weight based on the volume of the composition.

7. The use of any one of Claims 1-6, wherein said subject have no or inadequate response to VEGF inhibitor treatments and/or do not support invasive treatments for diabetic macular edema.

8. The use of any one of Claims 1-7, wherein said subject is selected among VEGFi naïve patients, with retinal thickening in the affected eye due to diabetic macular edema.

9. The use of any one of Claims 1-8, wherein the mean ETDRS Best Correct Visual Acuity is improved to at least 5 ETDRS letters at the end of the induction phase in subjects suffering from DME as compared to baseline.

10. The use of any one of Claims 1-9, wherein mean change of the central subfield thickness (CST) is reduced to more than -50μm CST as measured from baseline, after 6 weeks of treatment in said subjects suffering from DME.

11. The use of any one of Claims 1-10, wherein said eye drop formulation is preservative free.

12. The use of any one of Claims 1-11, wherein the dosing regimen comprises

(i) an induction phase of an eye drop formulation comprising 1.5% (w/v) dexamethasone, at a dosing of 6 drops a day for 6 weeks, followed by

(ii) a maintenance phase of said eye drop formulation at a dosing of 3 drops a day;

and wherein said eye drop formulation, comprises or essentially consists of:

- 1.5% of dexamethasone;
- 14% of γ-cyclodextrin;
- 2.5% of poloxamer;
- 0 to 0.2% of chelating agent;
- 0 to 1% of electrolyte;
- 0% to 0.6% of an additive to prevent the oxidation of the dexamethasone, and
- water;

the % being % by weight based on the volume of the composition.

13. The use of Claim 12, wherein the chelating agent is 0.1% (w/v) disodium edetate.

14. The use of any of Claims 12 or 13, wherein the electrolyte is 0.57% (w/v) sodium chloride.

15. The use of any of Claims 12-14, wherein the additive is sodium thiosulfate.