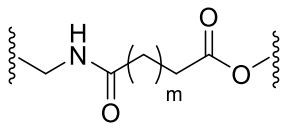
CLAIMS

1. A sustained release biodegradable ocular implant comprising a hydrogel and 200 to 800 µg axitinib,
wherein the hydrogel comprises crosslinked polyethylene glycol (PEG) units and the crosslinks between the PEG units include a group represented by the following formula



wherein m is 6,
wherein axitinib particles are dispersed within the hydrogel, and
wherein the implant is cylindrical and in its dry state has a length of less than 17 mm and a diameter of 0.1 mm to 0.5 mm,
for use in treating diabetic retinopathy (DR) in a patient in need thereof,
wherein the implant is administered by intravitreal injection.

2. The sustained release biodegradable ocular implant for use in treating DR of claim 1, wherein the implant is cylindrical and in its hydrated state (after 24 hours in phosphate-buffered saline at a pH of 7.2 at 37 °C) has a length of equal to or less than 10 mm and a diameter of equal to or less than 0.8 mm.

3. The sustained release biodegradable ocular implant for use in treating DR of any of the preceding claims, wherein the hydrogel comprises multi-arm PEG units that are the same or different, and that have a number average molecular weight of from 10,000 to 60,000 Daltons.

4. The sustained release biodegradable ocular implant for use in treating DR of any of the preceding claims, wherein the axitinib particles have a d90 particle size of less than 30 µm as determined by laser diffraction.

5. The sustained release biodegradable ocular implant for use in treating DR of any of the preceding claims, wherein the hydrogel biodegrades within 9 to 12 months.

6. The sustained release biodegradable ocular implant for use in treating DR of any of the preceding claims, wherein a treatment period with an implant is at least 3 months.

7. The sustained release biodegradable ocular implant for use in treating DR of any of the preceding claims, wherein a treatment period is 6 to 9 months.

8. The sustained release biodegradable ocular implant for use in treating DR of any of the preceding claims, wherein the treatment is a treatment of vascular leakage.

9. The sustained release biodegradable ocular implant for use in treating DR of any of the preceding claims, wherein the treatment is effective in improving the vision of the patient as expressed by the best corrected visual acuity (BCVA).

10. The sustained release biodegradable ocular implant for use in treating DR of claim 9, wherein the BCVA increases by at least 10 ETDRS letters, such as at least 15 ETDRS letters, such as at least 20 ETDRS letters during the treatment period.

11. The sustained release biodegradable ocular implant for use in treating DR of any of the preceding claims, wherein the implant is provided in a needle of gauge size 22 to 30.