~~CLAIMS~~

~~1. A sustained-release preparation comprising pioglitazone or a salt thereof, polyethylene oxide and a gel forming promoter, wherein the gel forming promoter is one kind or a combination of two or more kinds of water-soluble hydrophilic base selected from lactose, glucose, mannitol and trehalose; or one kind or a combination of two or more kinds of water-insoluble hydrophilic base selected from starch, partially pregelatinized starch, crospovidone, crystalline cellulose, carmellose calcium and carmellose.~~

CLAIMS

~~2~~1. ~~The sustained-release preparation according to claim 1,~~ A sustained-release preparation comprising pioglitazone or a salt thereof, polyethylene oxide and a gel forming promoter, wherein the gel forming promoter is one kind or a combination of two or more kinds of water-soluble hydrophilic bases selected from lactose, glucose, mannitol and trehalose; or one kind or a combination of two or more kinds of water-insoluble hydrophilic bases selected from starch, partially pregelatinized starch, crospovidone, crystalline cellulose, carmellose calcium and carmellose, and

~~wherein~~ the polyethylene oxide is

1) contained such that the product of the weight average molecular weight x 1/10000 and the content (%) of polyethylene oxide in the preparation is from (7×M+1500) to (14.5×M+5410), wherein M shows a value calculated by a weight average molecular weight of polyethylene oxide x 1/10000 when one kind of polyethylene oxide is used; or

2) contained such that the product of the weight average molecular weight x 1/10000 and the content (%) of polyethylene oxide having the highest average molecular weight among the polyethylene oxides used in the preparation is from (14×M-300) to (17×M+7700), wherein M shows a value calculated by a weight average molecular weight of polyethylene oxide having the highest average molecular weight ~~among the polyethylene oxides used~~ x 1/10000 when two or more kinds of polyethylene oxides having different average molecular weights are used.

~~3~~2. ~~The sustained-release preparation according to claim 1,~~ A sustained-release preparation comprising pioglitazone or a salt thereof, polyethylene oxide and a gel forming promoter, wherein the gel forming promoter is one kind or a combination

of two or more kinds of water-soluble hydrophilic bases selected from lactose, glucose, mannitol and trehalose; or one kind or a combination of two or more kinds of water-insoluble hydrophilic bases selected from starch, partially pregelatinized starch, crospovidone, crystalline cellulose, carmellose calcium and carmellose, and

~~wherein~~ the polyethylene oxide has a weight average molecular weight of not less than 1,000,000 and less than 4,000,000, and is contained at a ratio of 50 - 80 wt% of the preparation.

~~43~~. ~~The sustained-release preparation according to claim 1, A~~ sustained-release preparation comprising pioglitazone or a salt thereof, polyethylene oxide and a gel forming promoter, wherein the gel forming promoter is one kind or a combination of two or more kinds of water-soluble hydrophilic bases selected from lactose, glucose, mannitol and trehalose; or one kind or a combination of two or more kinds of water-insoluble hydrophilic bases selected from starch, partially pregelatinized starch, crospovidone, crystalline cellulose, carmellose calcium and carmellose, and

~~wherein~~ the polyethylene oxide has a weight average molecular weight of not less than 4,000,000 and not more than 10,000,000, and is contained at a ratio of 5 - 70 wt% of the preparation.

~~54~~. The sustained-release preparation according to claim 1 ~~or 2~~, which shows a dissolution ratio of pioglitazone of average 25-58% at the 2-hour time point, and average 60-100% at the 4-hour time point, in a dissolution test according to the 50 rpm USP Paddle Method and using pH 2.0 KCl/HCl buffer at 37°C as a test solution.

~~65~~. The sustained-release preparation according to any of claims 1 to ~~54~~, comprising 0.1 - 8 mg of pioglitazone; or a

salt of pioglitazone corresponding to 0.1 - 8 mg as pioglitazone.

~~7~~6. The sustained-release preparation according to claim ~~6~~5, comprising 0.1 mg, 0.3 mg, 0.5 mg, 0.8 mg, 2.8 mg or 5.2 mg of pioglitazone; or a salt of pioglitazone corresponding to 0.1 mg, 0.3 mg, 0.5 mg, 0.8 mg, 2.8 mg or 5.2 mg as pioglitazone.

~~8~~7. The sustained-release preparation according to any of claims 1 to ~~7~~6, wherein the pioglitazone or a salt thereof is pioglitazone hydrochloride.

~~9~~8. The sustained-release preparation according to any of claims 1 to ~~8~~7, which is a tablet.

~~10~~9. The sustained-release preparation according to claim ~~9~~8, which has a tablet weight of 60 - 600 mg.

~~11~~10. The sustained-release preparation according to any of claims 1 to ~~10~~9, wherein the pioglitazone or a salt thereof has an average particle size of 1 to 25 μm.

~~12~~11. A method of producing a sustained-release preparation, comprising
a step of granulating a mixture containing pioglitazone or a salt thereof, a gel forming promoter and polyethylene oxide while spraying an aqueous solution or dispersion containing a gel forming promoter, and compression-molding the obtained granules;
a step of granulating a mixture containing a gel forming promoter and polyethylene oxide while spraying an aqueous solution or dispersion containing a gel forming promoter, mixing the obtained granules with pioglitazone or a salt

thereof, and compression-molding the obtained mixture; or a step of compression-molding a mixture containing pioglitazone or a salt thereof, a gel forming promoter and polyethylene oxide,

wherein the gel forming promoter is one kind or a combination of two or more kinds of water-soluble hydrophilic bases selected from lactose, glucose, mannitol and trehalose; or one kind or a combination of two or more kinds of water-insoluble hydrophilic bases selected from starch, partially pregelatinized starch, crospovidone, crystalline cellulose, carmellose calcium and carmellose~~.~~, and

the polyethylene oxide is

1) contained such that the product of the weight average molecular weight x 1/10000 and the content (%) of polyethylene oxide in the preparation is from (7×M+1500) to (14.5×M+5410), wherein M shows a value calculated by a weight average molecular weight of polyethylene oxide x 1/10000 when one kind of polyethylene oxide is used; or

2) contained such that the product of the weight average molecular weight x 1/10000 and the content (%) of polyethylene oxide having the highest average molecular weight among the polyethylene oxides used in the preparation is from (14×M-300) to (17×M+7700), wherein M shows a value calculated by a weight average molecular weight of polyethylene oxide having the highest average molecular weight x 1/10000 when two or more kinds of polyethylene oxides having different average molecular weights are used.

12. A method of producing a sustained-release preparation, comprising

a step of granulating a mixture containing pioglitazone or a salt thereof, a gel forming promoter and polyethylene oxide while spraying an aqueous solution or dispersion containing a gel forming promoter, and compression-molding the obtained

granules;
a step of granulating a mixture containing a gel forming promoter and polyethylene oxide while spraying an aqueous solution or dispersion containing a gel forming promoter, mixing the obtained granules with pioglitazone or a salt thereof, and compression-molding the obtained mixture; or
a step of compression-molding a mixture containing pioglitazone or a salt thereof, a gel forming promoter and polyethylene oxide,
wherein the gel forming promoter is one kind or a combination of two or more kinds of water-soluble hydrophilic bases selected from lactose, glucose, mannitol and trehalose; or one kind or a combination of two or more kinds of water-insoluble hydrophilic bases selected from starch, partially pregelatinized starch, crospovidone, crystalline cellulose, carmellose calcium and carmellose, and
the polyethylene oxide has a weight average molecular weight of not less than 1,000,000 and less than 4,000,000, and is contained at a ratio of 50 - 80 wt% of the preparation.

13. A method of producing a sustained-release preparation, comprising
a step of granulating a mixture containing pioglitazone or a salt thereof, a gel forming promoter and polyethylene oxide while spraying an aqueous solution or dispersion containing a gel forming promoter, and compression-molding the obtained granules;
a step of granulating a mixture containing a gel forming promoter and polyethylene oxide while spraying an aqueous solution or dispersion containing a gel forming promoter, mixing the obtained granules with pioglitazone or a salt thereof, and compression-molding the obtained mixture; or
a step of compression-molding a mixture containing pioglitazone or a salt thereof, a gel forming promoter and

polyethylene oxide,
wherein the gel forming promoter is one kind or a combination of two or more kinds of water-soluble hydrophilic bases selected from lactose, glucose, mannitol and trehalose; or one kind or a combination of two or more kinds of water-insoluble hydrophilic bases selected from starch, partially pregelatinized starch, crospovidone, crystalline cellulose, carmellose calcium and carmellose, and
the polyethylene oxide has a weight average molecular weight of not less than 4,000,000 and not more than 10,000,000, and is contained at a ratio of 5 - 70 wt% of the preparation.

~~13~~14. Use of ~~pioglitazone or a salt thereof for the production of~~ the sustained-release preparation according to any of claims 1 to ~~11~~10 in the manufacture of a medicament ~~which is~~ for the prophylaxis and/or delayed onset or suppression of progression of Alzheimer's disease.