Claims

1. Use of a DPP-4 inhibitor, which is 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(*R*)-amino-piperidin-1-yl)-xanthine or a pharmaceutically acceptable salt thereof, for preparing a medicament for oral administration for treating and/or preventing of metabolic diseases in patients with moderate or severe renal impairment or end-stage renal disease, wherein said DPP-4 inhibitor in the medicament is to be administered in an oral dose of 5 mg per day to said patients.

2. The use according to claim 1, wherein the patients are ineligible for metformin therapy due to contraindication against metformin.

3. The use according to claim 1, wherein the patients are in need of reduced dose metformin therapy due to contraindication against metformin.

4. The use according to claim 3, wherein the medicament is for use in the treatment and/or prevention of type 2 diabetes mellitus in patients with moderate or severe renal impairment or end-stage renal disease.

6. The use according to any one of claims 1-5, wherein the medicament is for use in the treatment and/or prevention of type 2 diabetes mellitus in patients with renal disease, renal impairment or renal dysfunction, wherein said DPP-4 inhibitor in the medicament is to be used for said patients in the same dose as for patients with normal renal function.

7. The use according to any one of claims 1-6, wherein said DPP-4 inhibitor and its major active metabolite(s) have a relatively wide therapeutic window and/or are primarily eliminated via hepatic metabolism or biliary excretion.

8. The use according to any one of claims 1-7, wherein said DPP-4 inhibitor is excreted mainly via the liver.

9. The use according to any one of claims 1-8, wherein for said DPP-4 inhibitor excretion via the kidney represents a minor elimination pathway.

10. The use according to any one of claims 1-9, wherein said DPP-4 inhibitor is excreted mainly unchanged.

11. The use according to any one of claims 1-10, wherein for said DPP-4 inhibitor elimination via metabolism represents a minor elimination pathway.

1 and GLP-1 analogues, and insulin and insulin analogues, wherein said DPP-4 inhibitor in the composition is to be administered in an oral dose of 5 mg per day to said patients.

20. The use of a DPP-4 inhibitor, which is 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine, for preparing a pharmaceutical composition for oral administration for use in the treatment of type 2 diabetes mellitus in patients with moderate or severe renal impairment or end-stage renal disease, said composition being for use in combination with one or more further active substances selected from repaglinide, pioglitazone, and insulin and insulin analogues, wherein said DPP-4 inhibitor in the composition is to be administered in an oral dose of 5 mg per day to said patients.

21. Use of a DPP-4 inhibitor, which is 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(*R*)-amino-piperidin-1-yl)-xanthine, for preparing a medicament for oral administration for use in the treatment of type 2 diabetes mellitus in patients with moderate or severe renal impairment or end-stage renal disease, wherein said DPP-4 inhibitor in the medicament is to be administered in an oral dose of 5 mg per day to said patients.

22. Use of a DPP-4 inhibitor, which is 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(*R*)-amino-piperidin-1-yl)-xanthine, for preparing a medicament for oral administration for use in the treatment of type 2 diabetes mellitus in patients with moderate or severe renal impairment or end-stage renal disease, wherein said DPP-4 inhibitor is used for said patients in the same dose as for patients with normal renal function, wherein said DPP-4 inhibitor in the medicament is to be administered in an oral dose of 5 mg per day to said patients.

23. The use according to claim 21 or 22, wherein the patient has severe renal impairment or end-stage renal disease.

24. The use according to claim 21 or 22, wherein the patient has severe renal impairment.

25. Use of a DPP-4 inhibitor, which is 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine, for preparing a medicament for oral administration for use in the treatment and/or prevention of metabolic diseases, particularly diabetes (especially type 2 diabetes mellitus), in patients having chronic renal insufficiency or impairment of moderate, severe or terminal stage, wherein said DPP-4 inhibitor in the medicament is to be administered in an oral dose of 5 mg per day to said patients.

26 . Use according to any of the preceding claims, wherein 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine is to be used in a dosage of 5 mg for oral once daily administration.