This compound and methods for its preparation are disclosed in WO 2005/047297, WO 2008/109681 and WO 2009/009751. Specific salts are disclosed in WO 2008/027273 (including citrate, tartrate). A formulation of this compound is described in WO 2008/144730. For details, e.g. on a process to manufacture, to formulate or to use this compound or a salt thereof, reference is thus made to these documents.

- (2S,4S)-1-[2-[(4-ethoxycarbonylbicyclo[2.2.2]oct-1-yl)amino]acetyl]-4-fluoropyrrolidine-2-carbonitrile or a pharmaceutically acceptable salt thereof:

This compound and methods for its preparation are disclosed in WO 2005/075421, US 2008/146818 and WO 2008/114857. For details, e.g. on a process to manufacture, to formulate or to use this compound or a salt thereof, reference is thus made to these documents.

- 2-({6-[(3R)-3-amino-3-methylpiperidin-1-yl]-1,3-dimethyl-2,4-dioxo-1,2,3,4-tetrahydro-5H-pyrrolo[3,2-d]pyrimidin-5-yl}methyl)-4-fluorobenzonitrile or a pharmaceutically acceptable salt thereof, or 6-[(3R)-3-amino-piperidin-1-yl]-5-(2-chloro-5-fluoro-benzyl)-1,3-dimethyl-1,5-dihydro-pyrrolo[3,2-d]pyrimidine-2,4-dione or a pharmaceutically acceptable salt thereof:

These compounds and methods for their preparation are disclosed in WO 2009/084497 and WO 2006/068163, respectively. For details, e.g. on a process to manufacture, to formulate or to use these compounds or salts thereof, reference is thus made to these documents.

For avoidance of any doubt, the disclosure of each of the foregoing documents cited above is specifically incorporated herein by reference in its entirety.

Within the scope of the present disclosure it has now surprisingly been found that DPP-4 inhibitors as defined herein have surprising and particularly advantageous properties, which make them particularly suitable for treating and/or preventing (including preventing or slowing the progression) of metabolic diseases, particularly diabetes (especially type 2 diabetes mellitus) and conditions related thereto (e.g. diabetic complications), particularly in patients for whom metformin therapy is inappropriate due to intolerability or contraindication against metformin, such as patients ineligible for metformin therapy or patients in need of metformin dose reduction due to intolerability or contraindication against metformin.

In one aspect, there is provided 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.

In another aspect, there is provided 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 treating and/or preventing of metabolic diseases 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 sulphonylureas, thiazolidinediones, glinides, alpha-glucosidase blockers, GLP-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.

In another aspect, there is provided 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.

In another aspect, there is provided 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.

In another aspect, there is provided 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.

In another aspect, there is provided 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.