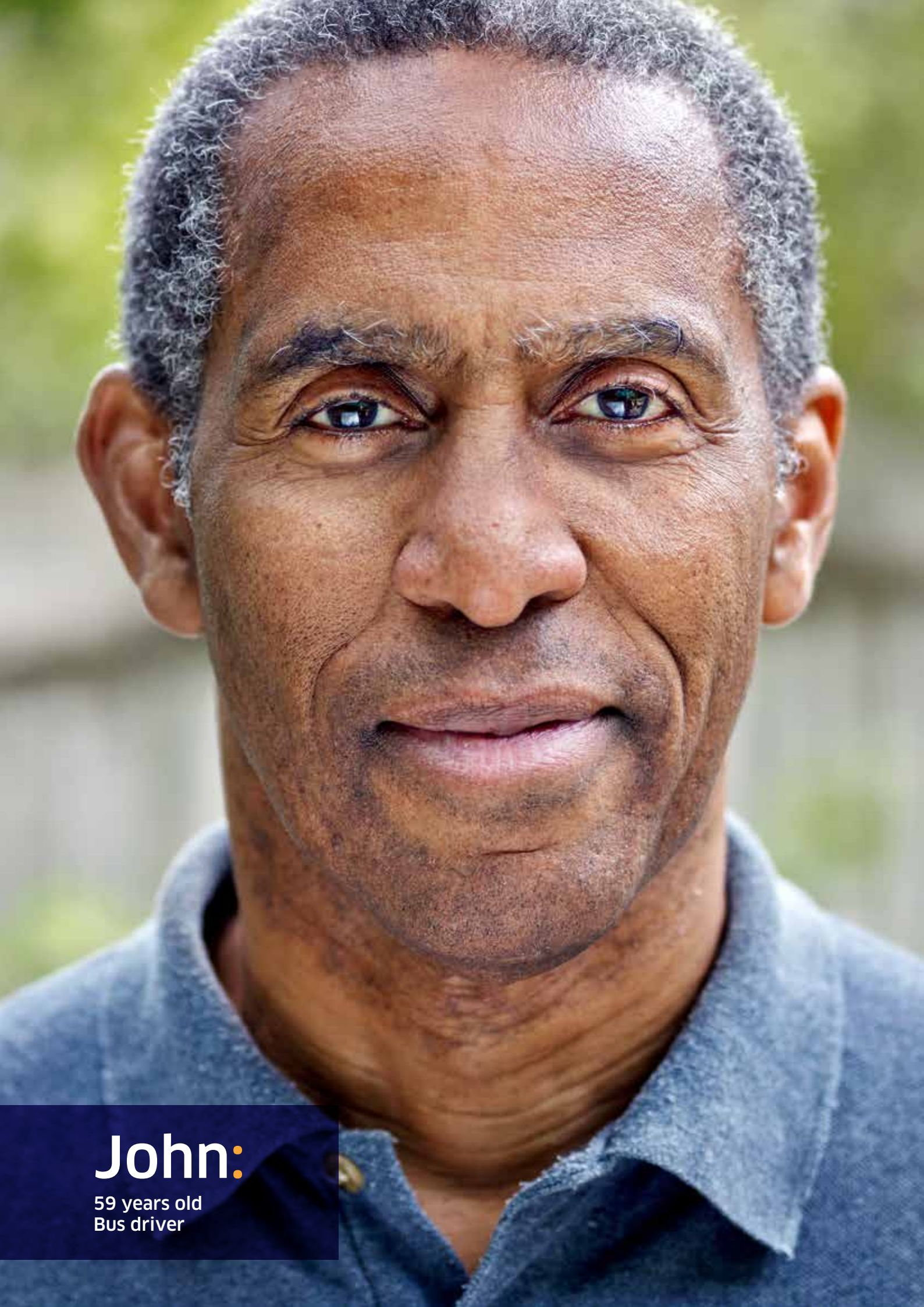
Trajenta®
(linagliptin) 5mg tablets

Have you seen a patient like John?

Boehringer Ingelheim

Lilly



John:

59 years old
Bus driver

JOHN:
Working-age T2D patient with microalbuminuria

Medical History

- T2D since 2014
- Hypertension since 2003

Physical Characteristics

- Height: 1.80 m
- Weight: 77 kg
- BMI: 23.8 kg/m^2
- BP: 141/87 mmHg

Notable Laboratory Results

- Fasting blood glucose: 152 mg/dL
- HbA_{1c}: 7.5%
- Total cholesterol: 193 mg/dL
- eGFR: 96 mL/min/1.73m^2
- UACR: 73 mg/g (last 108 and 91)

Clinic notes from today's visit

- John visits his primary care physician twice a year and his nurse every month to follow his hypertension and T2D
- He works long hours and has little time to exercise
- His blood pressure is usually stable on the high part of the normal range
- eGFR values are normal, but UACR is positive, and increasing for the last 5 years

Current Medications

- Metformin (1,000 mg BID)
- Irbesartan/Hydrochlorothiazide (150/12.5 mg QD)
- Amlodipine (10 mg QD)

What benefits does **TRAJENTA®** *offer to John?*

John has been diagnosed with T2D for less than 5 years, but he presents with long-standing hypertension. His HbA_{1c} is not bad, but not at goal. We need to reinforce diabetes treatment. He cannot be exposed to hypoglycaemia at his work. **TRAJENTA®** is a good option to help get John at control with a low risk of hypoglycaemia. The neutral effect of **TRAJENTA®** on weight is also a benefit for him. Poor glucose control and weight gain are drivers of UACR increase.[1-5]

BID: Bi-daily; BMI: Body mass index; BP: Blood pressure; eGFR: estimated glomerular filtration rate; QD: Once daily; UACR: Urinary albumin-to-creatinine ratio

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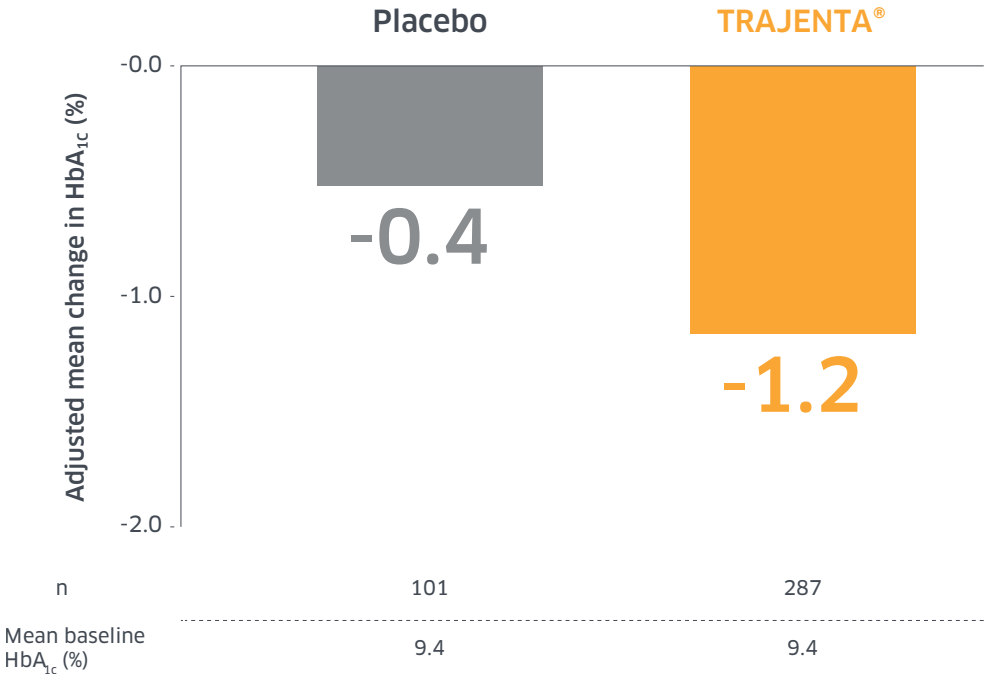
Proven efficacy in a once daily dose[1]

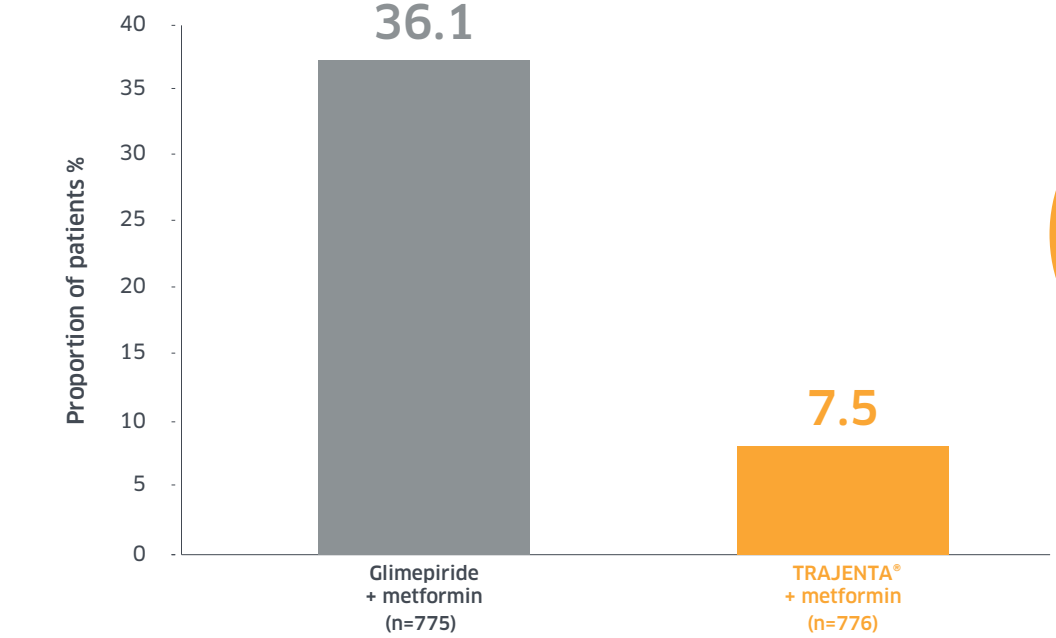
Adjusted mean HbA_{1c} change from baseline at 24 weeks in patients with high baseline HbA_{1c} values[1]*



0.8% placebo-corrected reduction p<0.0001

5 times less hypoglycaemia than SU[2]

Proportion of patients with at least one hypoglycaemic event for TRAJENTA® + metformin vs glimepiride + metformin†2*



5x less‡

* Pooled analysis of data from 2,258 subjects in three 24-week phase III, randomised, placebo-controlled, parallel-group studies, who received oral TRAJENTA® (5 mg/day) or placebo as monotherapy, added-on to metformin, or added-on to metformin plus sulphonylurea was performed. Adjusted mean HbA_{1c} change from baseline with TRAJENTA® was -1.2% (vs -0.4% with placebo, p<0.0001).

† Study performed using a free combination of linagliptin and metformin.

‡ 95% CI: 0.100, 0.186: p<0.0001. Hypoglycaemia as defined by the American Diabetes Association Workgroup on Hypoglycemia: American Diabetes Association Workgroup on Hypoglycemia. Diabetes Care 2005;28:1245–1249. 2 year double-blind, parallel group, active-controlled, non-inferiority study. Patients received linagliptin 5 mg once daily or glimepiride 1 mg once daily added to ongoing metformin. Glimepiride was uptitrated in 1 mg increments up to a maximum dose of 4 mg once daily at 4-week intervals during first 12 weeks of treatment. Primary endpoint: Change in HbA_{1c} from baseline. Two key secondary endpoints: occurrence of hypoglycaemic episodes up to 104 weeks and change in body weight from baseline to week 104.

Simple with 5mg, once daily for your T2D patients*[3]

5mg once daily[3]

Independent of:

Background T2D therapy†

Age‡

Hepatic function§

Kidney function

BMI

Disease duration

Ethnicity

* Indicated for use in adult patients. TRAJENTA® is contraindicated in those with hypersensitivity to any of the active substances or excipients, is not licensed for paediatric use and should not be used in pregnant women.

† Combination therapies studied with linagliptin were: Linagliptin as add-on to metformin therapy; Linagliptin as add-on to a combination of metformin and sulphonylurea therapy; Linagliptin as add-on to a combination of metformin and empagliflozin; Linagliptin as add-on to insulin therapy.

‡ No dose adjustment is necessary based on age. However, clinical experience in patients >80 years of age is limited and caution should be exercised when treating this population.

§ Pharmacokinetic studies suggest that no dose adjustment is required for patients with hepatic impairment but clinical experience in such patients is lacking.

BMI: Body mass index

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Placeholder for country abbreviated SmPC

References:
1) Del Prato S, et al. J Diab Compl. 2013;27:274–9. **2)** Gallwitz B, et al. Lancet. 2012;380:475–83. **3)** TRAJENTA® Summary of Product Characteristics. July 2018. **4)** Perkovic V, et al. Kidney Int. 2013;85(3):517-23. **5)** Rosenstock JL, et al.Front Med (Lausanne). 2018 30;5:122.