# Efficacy and Safety of Generic and Original Pioglitazone in Type 2 Diabetes Mellitus: A Multicenter, a Double-Blinded, Randomized-Controlled Study

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***Objective:*** *To compare the efficacy and safety of generic (Utmos®) and original (Actos®) 30 mg Pioglitazone tablets.*
***Study design:*** *A multicenter, parallel randomized, double-blinded, controlled study.*
***Material and Method:*** *Type 2 diabetic patients, with glycosylated hemoglobin ($HbA_{1c}$) ≥ 7.0%, who received Metformin not less than 1,000 mg/day over three months were recruited. Patients were randomized to receive either generic or original Pioglitazone 30 mg/day for 24 weeks.*
***Results:*** *Eighty-five patients were enrolled, forty-four patients received generic Pioglitazone and forty-one received original Pioglitazone. There were no significant differences in baseline characteristics between generic and original Pioglitazone group. There were significantly reduced $HbA_{1c}$, fasting plasma glucose (FPG) and significantly increased HDL-cholesterol from baseline ($p < 0.0001$) without statistically differences between the two groups. Headache and edema were found in both groups at comparable rates ($p > 0.05$).*
***Conclusion:*** *Generic Pioglitazone (Utmos®) is effective in controlling blood glucose and has similar effects on lipid profile as the original one. Both generic (Utmos®) and original (Actos®) 30 mg Pioglitazone tablets were not different in the efficacy and safety profiles.*

***Keywords:*** *Pioglitazone, Thiazolidinedione, Generic, Diabetes mellitus, Type 2*

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Type 2 diabetes, which accounts for 94% of those with diabetes[1], is caused by a combination of resistance to insulin action and an inadequate compensatory insulin secretory response[2]. Diet and exercise are the first line treatment for type 2 diabetes. However, most patients will require the addition of medications over the course of their diabetes. Only 30.7% of patients in Thailand achieved $HbA_{1c}$ of less than 7%[3].

A newer group of medication that decreases insulin resistance and increases insulin sensitivity is Thiazolidinediones (TZDs): Rosiglitazone and

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Pioglitazone. TZDs have demonstrated a 0.5-1.4% decrease in $HbA_{1c}$. They increase the sensitivity of muscle, fat, and liver to endogenous and exogenous insulin ("insulin sensitizers") and decrease insulin resistance which caused type 2 diabetes. The most common adverse effects are weight gain and fluid retention[4,5]. Pioglitazone improves lipid profile; decrease triglycerides (TG), increase high-density lipoprotein cholesterol (HDL-C), decrease low-density lipoprotein (LDL) particle concentration, LDL particle size[6] and reduces the need to add insulin to existing therapy[7]. In high-risk patients with type 2 diabetes and previous MI, Pioglitazone significantly reduced the occurrence of fatal and nonfatal MI and acute coronary syndrome[8].

The Thailand Diabetes Registry Project found that sixty-nine percent of patients received combination therapy and TZDs were commonly used[9]. With recent economic status, generic pioglitzone will help increase patients' access to this essential drug. The bioequivalence study of 30 mg Pioglitazone indicated that generic (Utmos®) and original (Actos®) Pioglitazone were bioequivalent in Thai healthy volunteers[10]. The objective of the present study were to compare the efficacy and safety of generic (Utmos®) and original (Actos®) 30 mg Pioglitazone tablets in type 2 diabetic patients. The primary objective was to compare the change of $HbA_{1c}$ and FPG between generic and original 30 mg Pioglitazone tablets. The secondary objective was to compare changes of lipid profile (total cholesterol (TC), triglycerides (TG), low-density lipoprotein (LDL-C) and high-density lipoprotein (HDL-C)) and safety (occurrence of side effects) between the two groups.

## Material and Method

The present study was a multicenter, double-blinded, parallel randomized-controlled study. The unachieved glycemic control type 2 diabetic patients, ages 30 to 70 years, with glycosylated hemoglobin ($HbA_{1c}$) $\geq$ 7.0% who received Metformin not less than 1,000 mg/day over three months were recruited from 7 Hospitals. Subjects were excluded if they were pregnant, breast-feeding or planning to get pregnant during the study; current users of TZDs; hypersensitivity to TZD; infected with HIV; or partake in other on going clinical trial; if they had AST, ALT more than 2.5 times the upper limit of normal; serum creatinine more than 1.8 mg/dl or 160 mmol/L; glomerulonephritis; coronary heart disease (CHD) or congestive heart failure (CHF); or recent history of drug and alcohol abuse.

The study was approved by the Ethics Committee of each participating hospital. Signed informed consent was obtained from all participants. Patients were randomized (1:1) to receive generic or original Pioglitazone 30 mg/day for 24 weeks. Randomization was stratified by center (computerized random numbers). Each center received generic and original Pioglitazone that were packed in opaque blister pack, sealed in aluminium moisture-barrier bag and labeled with random numbers. Patients attended the clinics for five study-visits: screening visit, randomized visit and subsequently at 4, 12 and 24 weeks after the randomized visit. Physical examination; body weight, waist circumference, blood pressure and pulse; were measured at every visit. $HbA_{1c}$ were analyzed at screening visit, 12 and 24 weeks at a central laboratory, Rajavithi hospital. Fasting plasma glucose (FPG), lipid profile and liver function were analyzed at screening visit and subsequently at 4, 12 and 24 weeks after the randomized visit. Repeated measures ANOVA were designed for analyzing changes in $HbA_{1c}$, FPG and lipid profile between baseline and each visit and between groups. T-test, Pearson Chi-square test and analysis of variance (f-test) were used to compare means of the various measurements between the two groups and within each group. A p-value less than 0.05 was considered as statistically significance. Data were analyzed by statistical program Minitab version 13. The sample size to give 95% confident interval and 90% power was calculated by repeated measures model[11].

## Results

Eighty-five patients were enrolled, forty-four patients received generic Pioglitazone and forty-one received original Pioglitazone. Patients were recruited from April 2008 to March 2009 and attended clinic visits at the time of randomization (baseline) and at week $4^{th}$, $12^{th}$ and $24^{th}$. Baseline characteristics of participants in both groups were similar as shown in Table 1.

$HbA_{1c}$, FPG, lipid profile and body weight during 24-week of treatment with generic and original 30 mg Pioglitazone tablets are shown in Table 2, Fig. 1 and Fig. 2. $HbA_{1c}$ reduction from baseline at week $12^{th}$ and $24^{th}$ in generic group were 0.76 and 0.91% ($p < 0.0001$) and in original group were 0.88 and 0.98%, respectively ($p < 0.0001$). FPG reduction from baseline at week $4^{th}$, $12^{th}$ and $24^{th}$ in generic group were 20.00, 24.93 and 23.93 mg/dl ($p < 0.0001$) and in original group were 21.75, 27.85 and 24.87 mg/dl, respectively

**Table 1.** Baseline demographics and clinical characteristics

| | Original (n = 41) mean ± SD | Generic (n = 44) mean ± SD | p-value |
|---|---|---|---|
| Age (year) | 55.41 ± 10.08 | 54.59 ± 7.65 | 0.671 |
| Female (n, %) | 29 (70.7%) | 36 (81.8%) | 0.229 |
| Body weight (kg) | 66.56 ± 13.44 | 67.20 ± 12.60 | 0.822 |
| Height (cm) | 157.48 ± 8.84 | 157.04 ± 7.04 | 0.803 |
| BMI ($kg/m^2$) | 26.59 ± 3.97 | 27.01 ± 4.30 | 0.638 |
| > 25 $kg/m^2$ (n, %) | 25 (61.0%) | 27 (61.4%) | 0.971 |
| Waist circumference (cm) | 90.10 ± 10.93 | 88.82 ± 10.43 | 0.581 |
| > 80 cm female, > 90 cm male (n, %) | 31 (75.6%) | 29 (65.9%) | 0.327 |
| Duration of DM (year) | 5.92 ± 5.29 | 6.11 ± 4.52 | 0.860 |
| Systolic BP (mmHg) | 129.32 ± 12.91 | 128.36 ± 12.10 | 0.726 |
| Diastolic BP (mmHg) | 77.37 ± 9.35 | 78.50 ± 7.39 | 0.535 |
| Hypertension (BP > 140/90) (n, %) | 8 (19.5%) | 10 (22.7%) | 0.717 |
| Pulse (times/min) | 75.41 ± 8.14 | 74.89 ± 6.55 | 0.742 |
| $HbA_{1c}$ (%) | 7.85 ± 0.61 | 7.72 ± 0.59 | 0.320 |
| Fasting plasma glucose (mg/dl) | 140.02 ± 24.66 | 137.73 ± 21.70 | 0.649 |
| Fasting plasma insulin (μU/ml) | 9.53 ± 6.27 | 10.93 ± 11.65 | 0.495 |
| Cholesterol (mg/dl) | 176.56 ± 31.46 | 178.80 ± 34.30 | 0.756 |
| Triglyceride (mg/dl) | 135.12 ± 43.66 | 157.84 ± 92.41 | 0.156 |
| LDL-C (mg/dl) | 104.58 ± 27.99 | 100.43 ± 29.57 | 0.510 |
| HDL-C (mg/dl) | 49.54 ± 10.56 | 51.86 ± 12.47 | 0.358 |
| Concomitant medications | | | |
| Statin (n, %) | 21 (51.2%) | 23 (52.3%) | 0.923 |
| Fibrate (n, %) | 3 (7.3%) | 6 (13.6%) | 0.344 |
| Beta blocker (n, %) | 5 (12.2%) | 10 (22.7%) | 0.203 |
| Diuretics (n, %) | 9 (22.0%) | 10 (22.7%) | 0.932 |
| ACE-I (n, %) | 11 (26.8%) | 16 (36.4%) | 0.345 |
| ARB (n, %) | 5 (12.2%) | 3 (6.8%) | 0.396 |
| CCB (n, %) | 11 (26.8%) | 9 (20.5%) | 0.489 |
| Aspirin (n, %) | 6 (14.6%) | 9 (20.5%) | 0.482 |

($p < 0.0001$). There were no significant differences in $HbA_{1c}$ and fasting plasma glucose (FPG) reduction between generic and original Pioglitazone group (p = ns).

Total cholesterol and LDL-cholesterol were not significantly changes and no differences between the original and the generic Pioglitazone. Triglycerides were decreased from baseline at week $4^{th}$, $12^{th}$ and $24^{th}$ 39.18, 29.43 and 39.25 mg/dl in generic group and 30.88, 22.02 and 24.05 mg/dl in original group, respectively ($p < 0.01$). HDL-cholesterol at week $4^{th}$, $12^{th}$ and $24^{th}$ were significantly increased from baseline 4.57, 5.69 and 6.73 mg/dl in generic group and 6.14, 7.19 and 5.58 mg/dl in original group, respectively ($p < 0.0001$).

Body weight at week $4^{th}$, $12^{th}$ and $24^{th}$ was increased from baseline 0.42, 1.26 and 1.86 kg in generic group and 0.73, 1.12 and 1.33 kg in original group, respectively ($p < 0.05$).

Headache and edema were found in both groups but not at different rates. Headache was 3 (6.8%) and 1 (2.4%) and edema was 8 (18.2%) and 7 (17.1%) in generic group and original group, respectively. No serious adverse event was reported throughout this study.

## Discussion

Type 2 diabetes, the most common form of diabetes, is characterized by insulin deficiency and resistance. Pioglitazone is an antihyperglycaemic agent that can increase insulin sensitivity and decrease insulin resistance. Because of its action on the major pathoetiology of type 2 diabetes, Pioglitazone is one of the antidiabetic agents commonly prescribed worldwide. The objective of the present study was to compare the efficacy and safety of generic (Utmos®) and original (Actos®) 30 mg Pioglitazone tablets in type 2 diabetes mellitus.

**Table 2.** $HbA_{1c}$, FPG, lipid profile and body weight during 24-month of treatment with generic and original 30 mg Pioglitazone tablets

| | Baseline mean ± SE | Week 4 mean ± SE | Week 12 mean ± SE | Week 24 mean ± SE |
|---|---|---|---|---|
| $HbA_{1c}$ (%) | | | | |
| Generic Pioglitazone | 7.72 ± 0.09 | - | 6.96 ± 0.11 | 6.81 ± 0.12 |
| Original Pioglitazone | 7.85 ± 0.10 | - | 6.97 ± 0.08 | 6.87 ± 0.10 |
| FPG (mg/dl) | | | | |
| Generic Pioglitazone | 137.73 ± 3.27 | 117.73 ± 3.23 | 112.80 ± 3.66 | 113.80 ± 4.00 |
| Original Pioglitazone | 140.02 ± 3.85 | 118.27 ± 2.86 | 112.17 ± 2.66 | 115.15 ± 2.71 |
| Fasting plasma insulin (μU/ml) | | | | |
| Generic Pioglitazone | 10.93 ± 1.76 | - | - | 8.09 ± 1.29 |
| Original Pioglitazone | 9.53 ± 0.98 | - | - | 7.95 ± 0.87 |
| Total cholesterol (mg/dl) | | | | |
| Generic Pioglitazone | 178.80 ± 5.17 | 177.93 ± 5.54 | 182.14 ± 5.59 | 182.55 ± 5.44 |
| Original Pioglitazone | 176.56 ± 4.91 | 176.00 ± 4.43 | 180.68 ± 5.07 | 178.95 ± 4.85 |
| Triglyceride (mg/dl) | | | | |
| Generic Pioglitazone | 157.84 ± 13.93 | 118.66 ± 7.45 | 128.41 ± 10.29 | 118.59 ± 7.61 |
| Original Pioglitazone | 135.12 ± 6.82 | 104.24 ± 5.58 | 113.10 ± 8.04 | 111.07 ± 7.97 |
| LDL-C (mg/dl) | | | | |
| Generic Pioglitazone | 100.43 ± 4.46 | 102.47 ± 4.88 | 103.10 ± 5.09 | 106.40 ± 5.43 |
| Original Pioglitazone | 104.58 ± 4.37 | 101.51 ± 3.71 | 104.52 ± 4.87 | 105.84 ± 4.51 |
| HDL-C (mg/dl) | | | | |
| Generic Pioglitazone | 51.86 ± 1.88 | 56.43 ± 2.18 | 57.55 ± 2.02 | 58.59 ± 2.07 |
| Original Pioglitazone | 49.54 ± 1.65 | 55.68 ± 1.76 | 56.73 ± 1.99 | 55.12 ± 2.02 |
| Body weight (kg) | | | | |
| Generic Pioglitazone | 67.20 ± 1.92 | 67.62 ± 1.93 | 68.46 ± 1.92 | 69.06 ± 1.94 |
| Original Pioglitazone | 66.56 ± 2.10 | 67.29 ± 2.05 | 67.68 ± 2.03 | 67.89 ± 2.06 |

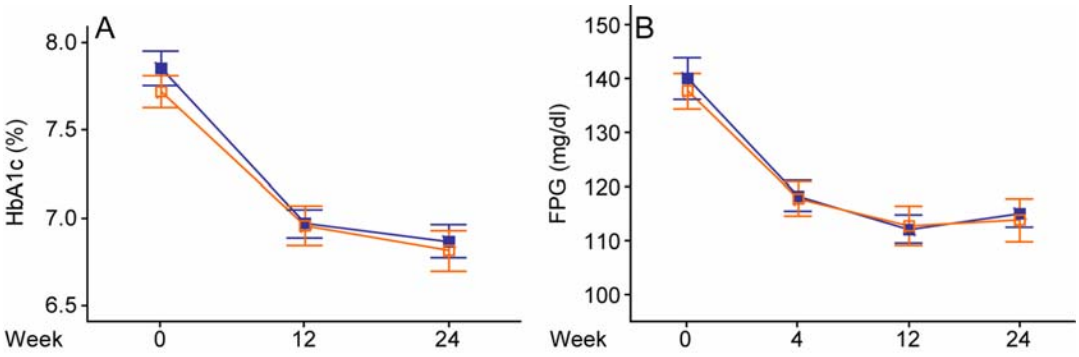


**Fig. 1** $HbA_{1c}$ (A), fasting plasma glucose; FPG (B) during 24-month of treatment with generic (□) and original (■) 30 mg Pioglitazone tablets (mean ± SE)

Results of the present study demonstrated that generic (Utmos®) and original (Actos®) 30 mg Pioglitazone tablets were not different in the efficacy and safety profiles. There were no statistically significant differences in $HbA_{1c}$ and fasting plasma glucose (FPG). $HbA_{1c}$ reductions from baseline at 24 weeks were 0.91% in generic and 0.98% in original group ($p < 0.0001$). FPG reductions from baseline in 24 weeks were 23.9 mg/dl in generic and 24.9 mg/dl in original ($p < 0.0001$). Starting with similar baseline $HbA_{1c}$ of participants in both groups 7.72% in generic and 7.85% in original, $HbA_{1c}$ were reduced to 6.81%

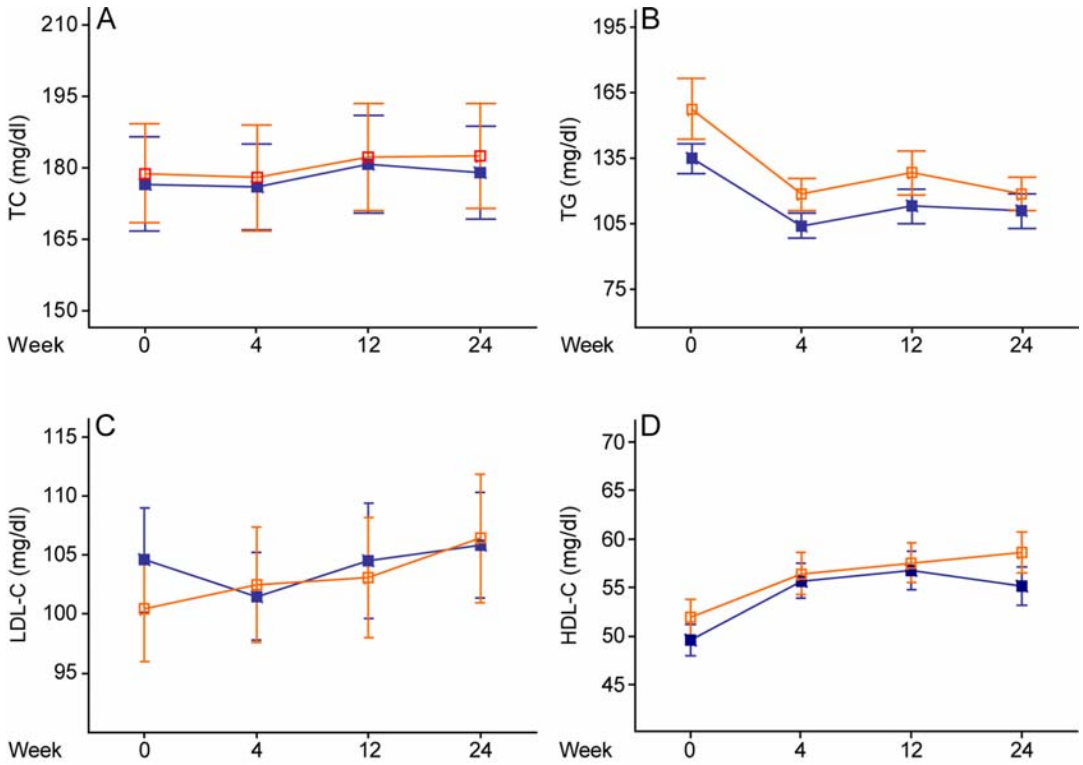


**Fig. 2** Total cholesterol; TC (A), triglyceride; TG (B), LDL-cholesterol (C) and HDL-cholesterol (D) during 24-month of treatment with generic (⊟) and original (■) 30 mg Pioglitazone tablets (mean ± SE)

in generic and 6.87% in original. In 24 weeks, generic achieved $HbA_{1c}$ goal ($HbA_{1c}$ < 7% ADA guideline[12]) in 31 case (70.45%) and original group in 22 case (53.66%). Combinations of Pioglitazone and metformin used in this study have benefit for achieving $HbA_{1c}$ goal without increasing risk of hypoglycemia.

Lipid profiles were changed in the same pattern and no significantly differences between groups. Triglyceride levels at week 24th were decreased from baseline by 39.3 mg/dl in generic group and 24.1 mg/dl in original group ($p < 0.01$). LDL-C levels at week 24th were increased from baseline by 5.97 mg/dl in generic group and 1.26 mg/dl in original group (p = ns). HDL-C levels at week 24th were increased from baseline by 6.73 mg/dl in generic group and 5.58 mg/dl in original group ($p < 0.0001$). The results showed that Pioglitazone have benefit for decreasing triglyceride and increasing HDL-cholesterol as a result of specific nuclear receptor activation (peroxisome-proliferator activated receptor-gamma and alpha [PPAR-gamma and PPAR-alpha]).

Body weights were increased in both groups but not significantly different between groups. At week 24th body weight was increased from baseline by 1.86 kg in generic group and 1.33 kg in original group ($p < 0.05$). Body weights of subjects in this study were increased in lower rate than previous reports (0.9-5.5 kg[5]). This may be the result of combination with metformin that attenuated the effect of Pioglitazone on body weight.

The present study revealed 19 adverse events. Headache was 3 (6.8%) and 1 (2.4%) and edema was 8 (18.2%) and 7 (17.1%) in generic and original group, respectively. There were no significant differences between groups. Congestive heart failure (CHF) was not found in both groups in this study. Nevertheless, TZDs must be used with caution in CHF and/or ankle edema patients. Headache was not severe and not related to blood pressure change. Pioglitazone was well tolerated and no patient withdrawn from this study.

Fasting Plasma Insulin was changed in the same pattern and no significant differences between generic and original group. Fasting Plasma Insulin was decreased by 2.84 μU/ml in generic group and

1.58 μU/ml in original group. Because Pioglitazone decreases peripheral insulin resistance, insulin requirement was decreased. This is a long-term benefit that helps preserve beta-cells function.

In conclusion, generic Pioglitazone 30 mg (Utmos®) is effective as original Pioglitazone 30 mg (Actos®) when combined with metformin in 24-week comparative study. There were no differences in metabolic control and safety findings.

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## *การศึกษาประสิทธิภาพ และความปลอดภัยของยาพิโอกลิตาโซนต้นแบบ และยาสามัญในผู้ป่วยโรคเบาหวานชนิดที่ 2*

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***วัตถุประสงค์:*** *เพื่อศึกษาเปรียบเทียบประสิทธิภาพ และความปลอดภัยของยาพิโอกลิตาโซนต้นแบบ และยาสามัญในผู้ป่วยโรคเบาหวานชนิดที่ 2*

***รูปแบบการศึกษา:*** *วิจัยเชิงทดลองแบบสหสถาบัน double-blinded, randomized-controlled study*

***วัสดุและวิธีการ:*** *ศึกษาในผู้ป่วยโรคเบาหวานชนิดที่ 2 ที่กำลังรักษาด้วยยา Metformin ขนาด 1,000 มก. หรือไม่ต่ำกว่า เป็นระยะเวลาอย่างน้อย 3 เดือน แต่ไม่สามารถควบคุมระดับน้ำตาลได้ตามเป้าหมาย คือมีระดับ $HbA_{1c}$ ≥ ร้อยละ 7.0 ผู้ป่วยถูกสุ่มให้ได้รับยาพิโอกลิตาโซนสามัญ (Utmos®) หรือต้นแบบ (Actos®) วันละ 30 มก. ต่อเนื่องเป็นเวลา 24 สัปดาห์*

***ผลการศึกษา:*** *ผู้ป่วยเข้าร่วมการศึกษาจำนวน 85 คน ได้รับยาพิโอกลิตาโซนสามัญจำนวน 44 คน และได้รับยาต้นแบบจำนวน 41 คน ไม่พบความแตกต่างทางสถิติ ระหว่างกลุ่มที่ได้รับยาพิโอกลิตาโซนสามัญและต้นแบบ ทั้งสองกลุ่มมีประสิทธิภาพในการลด $HbA_{1c}$, ระดับน้ำตาลในเลือดหลังอดอาหาร (FPG) และมีประสิทธิภาพในการเพิ่ม HDL อย่างมีนัยสำคัญทางสถิติ ($p < 0.0001$) เมื่อเปรียบเทียบจากเวลาเริ่มต้นการศึกษา อาการปวดศีรษะและบวมพบในทั้งสองกลุ่ม ($p > 0.05$)*

***สรุป:*** *ยาพิโอกลิตาโซนสามัญ (Utmos®) สามารถควบคุมระดับน้ำตาล และระดับไขมันในเลือดได้อย่างมีประสิทธิภาพเช่นเดียวกับยาต้นแบบ ยาพิโอกลิตาโซนสามัญ (Utmos®) และต้นแบบ (Actos®) มีประสิทธิภาพ และความปลอดภัยไม่แตกต่างกัน*