



DIABIZ-GM TABLETS

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Fixed dose combination of dapagliflozin, glimepiride and extended-release metformin tablets in patients with type 2 diabetes poorly controlled by metformin and glimepiride: A phase III, open label, randomized clinical study in India

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- To compare the safety and effectiveness of a triple fixed-dose combination (FDC) therapy of glimepiride + metformin hydrochloride extended-release (DAPA + GLIM + MET ER) tablets compared with the dual FDC of GLIM + MET PR tablets in Indian patients with type 2 diabetes mellitus (T2DM).
- In India, the population with type 2 diabetes has a high rate of cardiovascular and renal morbidity and mortality. Therefore, triple FDC of DAPA + GLIM + MET (ER) could accomplish targeted glycaemic control and prevent long-term problems and their associated morbidity.
- A phase III, randomized, open-label, active-controlled study was conducted for a maximum 30 weeks with randomization 1:1 in the two arms of FDCs.
- The proportion of patients achieving HbA1c <7.0% was significantly greater with the FDC of DAPA + GLIM + MET ER versus dual FDC at week 12 (19.1% vs. 6.5%; $p = 0.0002$) and week 16 (52.6% vs. 36.7%; $p = 0.0015$).

In individuals with poorly controlled type 2 diabetes on dual FDC therapy, once-daily FDC of DAPA + GLIM + MET ER was found to be effective in achieving glycemic control.

