

Benefits of Gloxiga-M®

(Dapagliflozin/Metformin)



1

Fixed-dose combination therapy with different, complementary mechanisms of action of drugs usually offers several advantages:¹

1. Fixed-dose therapy can simplify the dosing/ timing schedule and improve patient's adherence.
2. Low dose of drugs can achieve better efficacy compared with high dose of a single agent.
3. The risk of adverse events can be reduced benefiting from low doses of agents.
4. Fixed-dose combination therapy offers potential cost advantages that the price of fixed-dose formulation is usually comparable to or less than the total price of individual component.



2

Based on the left reasons discussed (part 1), the co administration of dapagliflozin and metformin, with complementary glucose lowering action, is considered as a promising treatment option for patients with inadequate glycemic control on metformin. In addition, this combination therapy has a low propensity to cause hypoglycaemia.¹



4

Bioequivalence has been established between the FDC of dapagliflozin/metformin (FDC tablets of either -2.5 -850/mg or -1000/-5mg strength) and the same doses coadministered as individual tablets; therefore, the efficacy and safety of the FDC* tablets and the combination of single-component tablets of dapagliflozin and metformin are also expected to be equivalent.²



3

Across clinical trials, GLOXIGA® , as initial combination therapy or as add-on, demonstrated significant reductions in glucose and body weight.³

	GLOXIGA® 10 mg + metformin XR	GLOXIGA® 10 mg + insulin	GLOXIGA® 10 mg + exenatide XR 2 mg + metformin
A1C REDUCTION mean change from BL (%)	-2.0%	-0.9%	-1.8%
	(n=211) (BL=9.1%) vs -1.4% for metformin XR alone (n=208) (P<0.0001)	(n=194) (BL=8.6%) vs -0.3% for insulin alone (n=193) (P<0.0001)	(n=228) (BL=9.3%) vs -1.4% for exenatide XR alone (n=230) (P<0.012)
Secondary end point WEIGHT REDUCTION mean change from BL weight (lb)	-7.3lb	-3.7lb	-7.5lb
	(n=211) (BL=195.3 lb) vs -3.1 lb for metformin XR alone (n=208) (P<0.0001)	(n=194) (BL=208.6 lb) vs 0 for insulin alone (n=193) (P<0.0001)	(n=198) (BL=203.1 lb) vs -3.4 lb for exenatide XR alone (n=192) (P<0.001)



Gloxiga-M[®]

5/850

Dapagliflozin 5/ Metformin 850



Gloxiga-M[®]

5/1000

Dapagliflozin 5/ Metformin 1000



Manufactured by Modava pharmaceutical company

*FDC: Fixed-dose combination.

REFERENCES

1. Combination therapy for type 2 diabetes: dapagliflozin plus metformin Xueying Tan & Jingbo Hu To cite this article: Xueying Tan & Jingbo Hu (2015): Combination therapy for type 2 diabetes: dapagliflozin plus metformin, Expert Opinion on Pharmacotherapy, DOI: 10.1517/14656566.2016.1121235 To link to this article: <http://dx.doi.org/10.1517/14656566.2016.1121235>.
2. Bioequivalence of Fixed-Dose Combinations of Dapagliflozin and Metformin with Single-Component Tablets in Healthy Subjects and the Effect of Food on Bioavailability Tjerk W.A. de Bruin¹, Stots Reelee², Jennifer E. Hamer-Maansson³, Shamik Parikh¹, and Weifeng Tang¹ Clinical Pharmacology in Drug Development 2016, 5(2) 118-130 ©2015, The American College of Clinical Pharmacology DOI: 10.1002/cpdd.220.
3. Frías JP, Guja C, Hardy E, et al. Exenatide once weekly plus dapagliflozin once daily versus exenatide or dapagliflozin alone in patients with type 2 diabetes inadequately controlled with metformin monotherapy (DURATION-8): a 28 week, multicentre, double-blind, phase 3, randomised controlled trial. Lancet Diabetes Endocrinol. 2016;4(12):1004-1016.



Head office: 5th floor, No. 275, Shahid Beheshti Ave, Tehran, IRAN
 Tel: +98 21 88174996-88173928 Fax: +98 21 88174917
 www.modavapharma.com info@modavapharma.com @Modavapharma