ema المترجمة لغة المرجع المعتمد Nowhan Saeed 8/7/2018

Dapaveldactin Plus 5 mg/850 mg film-coated tablets
Dapaveldactin Plus 5 mg/1,000 mg film-coated tablets
Dapagliflozin/Metformin hydrochloride

1. NAME OF THE MEDICINAL PRODUCT

Dapaveldactin Plus 5 mg/850 mg film-coated tablets

Dapaveldactin Plus 5 mg/1000 mg film-coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Dapaveldactin Plus 5 mg/850 mg film-coated tablets

Each tablet contains dapagliflozin propanediol monohydrate equivalent to 5 mg dapagliflozin and 850 mg of metformin hydrochloride.

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3. PHARMACEUTICAL FORM

Film-coated tablet (tablet).

Dapaveldactin Plus 5 mg/850 mg film-coated tablets

Light Brown to Brown oblong biconvex unscored film-coated tablets.

Dapaveldactin Plus 5 mg/1,000 mg film-coated tablets

Yellow to Dark beige oblong biconvex unscored film-coated tablets.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Dapaveldactin Plus is indicated in adults aged 18 years and older with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control:

- in patients inadequately controlled on their maximally tolerated dose of metformin alone
- in combination with other glucose-lowering medicinal products, including insulin, in patients inadequately controlled with metformin and these medicinal products
- in patients already being treated with the combination of dapagliflozin and metformin as separate tablets.

4.2 Posology and method of administration

Posology

Adults with normal renal function (GFR ≥ 90 mL/min)

LAPTIS EGYPT Registration department