



RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Korlym (mifepristone) is a potent antagonist of progesterone and cortisol via progesterone and glucocorticoid (GR-II) receptor respectively, which affects the hypothalamic-pituitary-adrenal (HPA) axis to further increase circulating cortisol levels while, at the same time, blocking their effects. Korlym does not decrease cortisol production but reduces the effects of excess cortisol (e.g., hyperglycemia). The antiprogestational effects will result in the termination of pregnancy. It has been approved to control hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery (1).

Regulatory Status

FDA-approved indication: Korlym is a cortisol receptor blocker indicated to control hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery (1).

Limitations of Use:

Korlym cannot be used in the treatment of patients with type 2 diabetes mellitus unrelated to endogenous Cushing's syndrome (1).

Korlym carries a boxed warning regarding termination of pregnancy resulting from the antiprogestational effects of the drug. Pregnancy must be excluded before the initiation of treatment with Korlym, or if treatment is interrupted for more than 14 days in females of reproductive potential (1).

The use of Korlym in women with a history of unexplained vaginal bleeding and endometrial hyperplasia with atypia or endometrial carcinoma is also contraindicated (1).

Korlym should be used with caution in patients with certain conditions including adrenal insufficiency, hypokalemia, vaginal bleeding, and QT prolongation. Dosage should not exceed 600mg a day in patients with renal impairment or mild to moderate hepatic impairment. Korlym



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KORLYM (mifepristone)

should not be used in patients with severe hepatic impairment (1).

Safety and effectiveness have not been established in pediatric patients (1).

Summary

Korlym (mifepristone) is a potent antagonist of progesterone and cortisol. It is indicated to control hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery. Korlym carries a boxed warning regarding termination of pregnancy. The use of Korlym in women with a history of unexplained vaginal bleeding and endometrial hyperplasia with atypia or endometrial carcinoma is also contraindicated. Korlym should be used with caution in patients with certain conditions including adrenal insufficiency, hypokalemia, vaginal bleeding, and QT prolongation. Safety and effectiveness have not been established in pediatric patients (1).

Prior approval is required to ensure the safe, clinically appropriate and cost-effective use of Korlym while maintaining optimal therapeutic outcomes.

References

1. Korlym [package insert]. Menlo Park, CA: Corcept Therapeutics Inc.; November 2019.