



PHENTOLAMINE POWDER (phentolamine)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Phentolamine is a vasodilator, which acts by producing an alpha-adrenergic blockade which causes the vessels to expand for a short duration. This mechanism of action allows phentolamine to be used clinically in various hypertensive crisis, dermal necrosis and sloughing following intravenous administration or extravasation of norepinephrine and aiding in the diagnosis of pheochromocytoma (1).

Regulatory Status

FDA-approved indications: Phentolamine powder is indicated for the prevention or control of hypertensive episodes that may occur in a patient with pheochromocytoma as a result of stress or manipulation during preoperative preparation and surgical excision. Phentolamine is also indicated in the prevention or treatment of dermal necrosis and sloughing following intravenous administration or extravasation of norepinephrine and used in the diagnosis of pheochromocytoma by the phentolamine blocking test (1).

The phentolamine blocking test is most reliable in detecting pheochromocytoma in patients with sustained hypertension and least reliable in those with paroxysmal hypertension. False-positive tests may occur in patients with hypertension without pheochromocytoma (1).

Phentolamine is contraindicated in myocardial infarction, history of myocardial infarction, coronary insufficiency, angina, or other evidence suggestive of coronary artery disease; hypersensitivity to phentolamine or related compounds (1).

Off-Label Use:

Off-label (non-FDA approved) compounded topical preparations of phentolamine have not been proven safe or effective.

Phentolamine for treatment of erectile dysfunction (ED) is excluded from coverage.

Summary

Phentolamine is a vasodilator, which acts by producing an alpha-adrenergic blockade which causes the vessels to expand for a short duration. This mechanism of action allows

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phentolamine to be used clinically in various hypertensive crisis, dermal necrosis and sloughing following intravenous administration or extravasation of norepinephrine, and the diagnosis of pheochromocytoma. The phentolamine blocking test is not the procedure of choice and should be reserved for cases in which additional confirmatory evidence is necessary and the relative risks involved in conducting the test have been considered. Phentolamine is contraindicated in myocardial infarction, history of myocardial infarction, coronary insufficiency, angina, or other evidence suggestive of coronary artery disease; hypersensitivity to phentolamine or related compounds (1).

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

References

1. Phentolamine mesylate [package insert]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; March 2024.