

Drug of the Month
Widaplik™
Treatment for hypertension

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use WIDAPLIK™ safely and effectively. See full prescribing information for WIDAPLIK. WIDAPLIK (telmisartan, amlodipine and indapamide) tablets, for oral use Initial U.S. Approval: 2025 **WARNING: FETAL TOXICITY** See full prescribing information for complete boxed warning. • When pregnancy is detected, discontinue WIDAPLIK as soon as possible (5.1, 8.1) • Drugs that act directly on the renin-angiotensin-aldosterone system can cause injury and death to the developing fetus (5.1, 8.1)

-----INDICATIONS AND USAGE-----

WIDAPLIK is a combination tablet of telmisartan, an angiotensin II receptor blocker, amlodipine, a dihydropyridine calcium channel blocker and indapamide, a thiazide-like diuretic. Widaplik is indicated for the treatment of hypertension, including as initial treatment, to lower blood pressure. (1) Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. (1)

-----DOSAGE AND ADMINISTRATION-----

For initial treatment of hypertension, start with Widaplik (10 mg/ 1.25 mg/0.625 mg) or Widaplik (20 mg/2.5 mg/1.25 mg) orally once daily. Titrate up to a maximum dose of Widaplik (40 mg/5 mg/2.5 mg) orally once daily. (2.2) Dosage may be increased after 2 weeks to a maximum dose of 40 mg/5 mg/2.5 mg orally once daily to achieve more rapid control. (2.1) Almost all of the antihypertensive effect is apparent within 2 weeks of initiating treatment. (2.1)

-----DOSAGE FORMS AND STRENGTHS-----

Tablets: (telmisartan/amlodipine/indapamide) 10 mg/1.25 mg/ 0.625 mg, 20 mg/2.5 mg/1.25 mg, 40 mg/5 mg/2.5 mg (3)

-----CONTRAINDICATIONS-----

- Known hypersensitivity (e.g., anaphylaxis or angioedema) to telmisartan, amlodipine, indapamide, or to other sulfonamide-derived drugs, or to any other component of this product (4)
- Do not co-administer aliskiren with Widaplik in patients with diabetes (4) • Anuria (4)

-----WARNINGS AND PRECAUTIONS-----

- Hypotension: Correct volume depletion prior to initiation (5.2) • Electrolyte and Glucose Imbalances: Monitor serum electrolytes and glucose (5.3) • Impaired Renal Function: Monitor

renal function (5.4) • Acute angle closure glaucoma can develop (5.5) • Hyperuricemia may occur (5.6)

-----ADVERSE REACTIONS-----

The most common adverse reaction is symptomatic hypotension. Low sodium and potassium values were recorded more often with Widaplik compared to placebo (6.1). To report SUSPECTED ADVERSE REACTIONS, contact George Medicines Pty Limited at 1-888 508-2083 or FDA at 1-800-FDA1088 or www.fda.gov/medwatch.

-----DRUG INTERACTIONS-----

• NSAIDs: Increased risk of renal impairment and loss of antihypertensive effect (7.1) • If simvastatin is co-administered with Widaplik, do not exceed doses greater than 20 mg daily of simvastatin (7.2) • Do not co-administer aliskiren with Widaplik in patients with diabetes (7.1)

-----USE IN SPECIFIC POPULATIONS-----

• Lactation: Breastfeeding is not recommended (8.2) • Geriatric Patients: Severe cases of hyponatremia, accompanied by hypokalemia have been reported with use of indapamide in elderly females; consider initiation at lower doses for patients ≥ 65 years of age (8.5) • Hepatic Impairment: Monitor carefully and start treatment at low doses (8.6)

See 17 for PATIENT COUNSELING INFORMATION and FDA approved patient labeling.
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