Low-Dose Chlorthalidone Granted FDA Approval for Treatment of Adults With Hypertension

Key Takeaways

- FDA approval of 12.5-mg chlorthalidone provides a new low-dose option for hypertension management, enhancing treatment flexibility.
- Chlorthalidone is effective in reducing cardiovascular risks and is recommended in clinical guidelines for its benefits and prolonged half-life.
- Pharmacists should monitor for adverse effects like electrolyte imbalances and counsel patients on the benefits of lower doses, particularly for the elderly.

The 12.5-mg dose tablet enhances hypertension treatment options and reduces adverse effects for patients.

The FDA has granted regulatory approval to 12.5-mg chlorthalidone (HemiClor; PRM Pharma, LLC) tablets, indicated for the lowering of blood pressure in adults with hypertension, according to a news release by PRM Pharma. This novel, low-dose option joins 25-mg and 50-mg higher-dose formulations of chlorthalidone that have been available in the United States and could aid pharmacists in the management of dose-related adverse effects.[1]

New Dose Could Lower Rates of Adverse Events

"Chlorthalidone has played a key role in hypertension treatment strategies for decades," William B. White, MD, professor emeritus at the University of Connecticut School of Medicine and past president of the American Society of Hypertension, said in the news release. "Having access to a 12.5 mg dose in the US may offer clinicians additional flexibility when initiating therapy and aligns with current treatment recommendations for many adult patients with stage 1 or stage 2 hypertension."[1]

Initially approved in 1960, chlorthalidone has remained an effective oral treatment for managing hypertension. It is a thiazide-like diuretic, which has been historically found to be effective at preventing major forms of cardiovascular disease that are associated with hypertension while being less expensive and more accessible for patients.[2,3]

Landmark trials assessing chlorthalidone in patients with hypertension have initiated treatment with a 12.5-mg dose, with investigators finding the dose to be safe and effective at reducing the risk of cardiovascular events. This data indicates that the use of 12.5 mg chlorthalidone when starting treatment should be recommended by pharmacists and treatment providers to initiate antihypertensive therapy or serve as an add-on therapy with additional blood pressure reduction methods.[1]

Clinical practice guidelines have implemented chlorthalidone into their recommendations, including the 2017 ACC/AHA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults. Those guidelines, and others, recommend chlorthalidone as a preferred diuretic because of its cardiovascular outcome benefits and prolonged half-life, which extends the effectiveness of treatment. FDA’s approval of 12.5-mg chlorthalidone will now provide clinicians and pharmacists with a guideline-adherent treatment option for hypertension.[1,4]

Considerations for Pharmacists

The package insert for chlorthalidone indicates potential complications with its use. Importantly, chlorthalidone is contraindicated in patients with anuria or those with a known hypersensitivity to chlorthalidone or sulfonamide-derived drugs. Furthermore, common adverse reactions possible with chlorthalidone treatment include electrolyte imbalance, dizziness, and gastrointestinal discomfort. Pharmacists should consistently monitor patients for changes to their cardiometabolic levels, including blood sugar levels.[1,2]

"We are proud to introduce [chlorthalidone] as a new treatment option for adults with hypertension,” Joseph T. McDevitt, president and CEO. “Lower effective doses may offer a more individualized approach to initiating therapies, particularly for elderly patients who are more susceptible to dose-related adverse effects.”[1]

Chlorthalidone 12.5-mg tablets are expected to be available in pharmacies across the US beginning in May 2025. As the product becomes available in more locations, pharmacists should be prepared to counsel patients on the benefits of a lower dose of chlorthalidone in relation to a patient's blood pressure levels. Patients who are currently being treated with higher doses of the medication may have lower rates of adverse events with a reduced dose and should discuss options with their treatment provider.[1]

REFERENCES

1. PRM Pharma, LLC. FDA approves new, low dose chlorthalidone for the treatment of hypertension: HemiClor (12.5 mg chlorthalidone). News Release. Released April 16, 2025. Accessed May 7, 2025. https://img1.wsimg.com/blobby/go/67a3c0a7-e67f-4613-a07e-5d78278cdc2c/downloads/a0590e2b-3018-49e1-8a32-dab802625e47/HemiClor_Press%20Release.pdf?ver=1746459316136
2. Drugs.com. HemiClor: Package insert/prescribing info. Last Updated April 7, 2025. Accessed May 7, 2025. https://www.drugs.com/pro/hemiclor.html
3. ALLHAT Officers and Coordinators for ALLHAT Collaborative Research Group. Major outcomes in high-risk hypertensive patients randomized to angiotensin-converting enzyme inhibitor or calcium channel blocker vs diuretic: The antihypertensive and lipid-lowering treatment to prevent heart attack trial (ALLHAT). JAMA Netw Open. 2002;288(23):2981-2997. doi:10.1001/jama.288.23.2981
4. Whelton PK, Carey RM, Aronow WS, et al. 2017 ACC/AHA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: Executive Summary. Hypertension. 2018;71(6):1269-1324. doi:10.1161/HYP.0000000000000066

News Source:

https://www.pharmacytimes.com/view/low-dose-chlorthalidone-granted-fda-approval-for-treatment-of-adults-with-hypertension