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PRESS RELEASE

FDA Approves New, Low-Dose Chlorthalidone for the Treatment of Hypertension in Adults: HemiClor™ (12.5 mg chlorthalidone)

HemiClor™ chlorthalidone 12.5 mg

West Conshohocken, PA—April 16, 2025—PRM Pharma, LLC today announced the U.S. Food and Drug Administration (FDA) approval of HemiClor (12.5 mg chlorthalidone) tablets for the treatment of hypertension in adults, to lower blood pressure.

Chlorthalidone, a thiazide-like diuretic, has been studied extensively over several decades in the treatment of hypertension. It is recognized in the 2017 ACC/AHA Guideline for the Prevention, Detection, Evaluation and Management of High Blood Pressure in Adults as the preferred diuretic based on its prolonged half-life and evidence of cardiovascular outcome benefits.[1] Landmark studies such as the ALLHAT and SHEP trials, sponsored by the National Heart, Lung, and Blood Institute, demonstrated that stepped-care treatment strategies—which often began with 12.5 mg of chlorthalidone—were effective in reducing the risk of cardiovascular events.[2,3] These findings support the use of 12.5 mg as the recommended starting dose in current hypertension treatment guidelines, either to initiate antihypertensive therapy or to serve as add-on therapy when additional blood pressure reduction is needed.[1,4]

HemiClor now provides U.S. patients and healthcare professionals access to a 12.5 mg chlorthalidone tablet formulation that aligns with guideline recommendations. Until now, only higher-dose chlorthalidone tablets (25 mg and 50 mg) have been available in the U.S. This new low-dose option may help clinicians better individualize therapy and potentially reduce the risk of dose-related side effects. As noted in the approved prescribing information, metabolic adverse effects such as hypokalemia and hyperuricemia are dose-related; thus, a lower starting dose may help mitigate these risks when initiating treatment.[5]

“Chlorthalidone has played a key role in hypertension treatment strategies for decades,” said William B. White, M.D., Professor Emeritus at the University of Connecticut School of Medicine and past president of the American Society of Hypertension. “Having access to a 12.5 mg dose in the U.S. 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.”

Joseph T. McDevitt, President and CEO of PRM Pharma, LLC, added, “We are proud to introduce HemiClor as a new treatment option for adults with hypertension. Our mission is to address unmet clinical needs by developing low-dose pharmaceutical products that support evidence-based care. 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.”

HemiClor (12.5 mg chlorthalidone tablets) is expected to be available in pharmacies nationwide beginning in May 2025.

Indication and Usage

HemiClor (chlorthalidone) is indicated for the treatment of hypertension to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. These benefits have been demonstrated in controlled trials of antihypertensive drugs from a wide variety of pharmacologic classes, including chlorthalidone.

Important Safety Information

- Contraindications: HemiClor is contraindicated in patients with anuria or known hypersensitivity to chlorthalidone or sulfonamide-derived drugs.
- Adverse Reactions: The most common adverse reactions observed with chlorthalidone include electrolyte imbalance (particularly hypokalemia), dizziness, and gastrointestinal discomfort.
- Monitoring: Periodic monitoring of serum electrolytes is recommended.
- Chlorthalidone may increase blood sugar levels, affect diabetes control, and cause changes in the need for diabetes medication
- Drug Interactions: Chlorthalidone may potentiate the effects of other antihypertensive agents and may interact with lithium, antidiabetics, or NSAIDs.

These are not all the possible side effects of Chlorthalidone. Please see the full Prescribing Information, available at www.prmpharma.com, for complete efficacy and important safety Information.

About PRM Pharma, LLC

PRM Pharma, LLC is a privately held specialty pharmaceutical company based in Pennsylvania, focused on developing low-dose therapies to support clinical practice guidelines and improve patient care. www.prmpharma.com

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To report suspected adverse reactions, contact PRM Pharma at info@prmpharma.com or the FDA at www.fda.gov/medwatch or 1-800-FDA-1088.

References

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