PRM Pharma and Ingenus Pharmaceuticals Announce Orange Book Listing of Patent Protecting HemiClor® Formulation Technology



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WEST CONSHOHOCKEN, Pa., July 28, 2026 /PRNewswire/ -- PRM Pharma, LLC, the NDA holder and marketer of HemiClor® (chlorthalidone tablets, 12.5 mg), and Ingenus Pharmaceuticals, LLC, the developer, manufacturer, and patent owner, today announced that the U.S. Food and Drug Administration (FDA) has listed U.S. Patent No. 12,667,554 B1 in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book) for HemiClor.

The patent protects the proprietary formulation technology incorporated into the first and only FDA-approved 12.5 mg chlorthalidone tablet through 2045, strengthening the intellectual property supporting HemiClor.

HemiClor (chlorthalidone tablets, 12.5 mg) is indicated for the treatment of hypertension in adults to lower blood pressure.

HemiClor is available by prescription through retail pharmacies nationwide. Patients may be able to reduce their out-of-pocket cost through third-party prescription savings programs. Program terms, participating pharmacies, and savings may vary.

Innovation in an Established Medicine

Although chlorthalidone has been used for decades, developing a 12.5 mg tablet that met FDA approval requirements involved overcoming formulation challenges involving dissolution, particle characteristics, stability, and manufacturability. The patented formulation technology enabled development of a commercially manufactured 12.5 mg chlorthalidone tablet that can be administered whole, eliminating the need for tablet splitting.

HemiClor was developed to provide healthcare professionals with the first FDA-approved 12.5 mg chlorthalidone tablet that corresponds to a guideline-recommended starting dose for many adults initiating chlorthalidone therapy.[2] Major hypertension guidelines recognize chlorthalidone as a preferred thiazide-type diuretic because of its long duration of action and cardiovascular outcomes data, and more recent guidelines recommend optimizing chlorthalidone therapy as part of treatment strategies for resistant hypertension.[2,3]

Why the Orange Book Listing Matters

The Orange Book listing protects HemiClor's proprietary formulation technology through 2045. Under the Hatch-Waxman Act, future applicants seeking approvals through an Abbreviated New Drug Application (ANDA) must provide patent certifications addressing Orange Book-listed patents during the FDA review process.

Together, FDA approval, guideline-aligned dosing, and Orange Book-listed proprietary formulation technology distinguish HemiClor as an innovative advancement for a well-established antihypertensive medicine.

Executive Statements

"HemiClor demonstrates that meaningful innovation remains possible even for well-established medicines," said Joe McDevitt, President and CEO of PRM Pharma. "HemiClor provides healthcare professionals with an FDA-approved 12.5 mg chlorthalidone

treatment option that aligns with current hypertension guidelines.[2,3] In addition, certain metabolic side effects associated with chlorthalidone are dose related and may occur more frequently at higher doses.[1] The Orange Book listing further reinforces the proprietary formulation technology underlying this important advancement."

"Developing a commercially robust 12.5 mg chlorthalidone tablet required much more than reducing the dose," said Mukteeshwar Gande, M.S., R.Ph., Chief Scientific Officer of RiconPharma and inventor of the patented technology. "Our patented formulation technology addresses key pharmaceutical challenges while delivering a differentiated product designed to address an important clinical need. The Orange Book listing highlights the innovation behind HemiClor and our commitment to advancing pharmaceutical science."

Indication

HemiClor (chlorthalidone tablets, 12.5 mg) is indicated for the treatment of hypertension in adults to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. Full Prescribing Information is available at **www.hemiclor.com**.

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 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 for complete information.[1]

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.

About Ingenus Pharmaceuticals, LLC

Ingenus Pharmaceuticals, LLC is a specialty pharmaceutical company focused on the development, manufacturing, and lifecycle management of high-quality pharmaceutical products. Ingenus is the patent owner and manufacturer of HemiClor.

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