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Generic Name:

Ambrisentan

Trade Name:

Letairis

Company:

Multiple manufacturers

Notes:

FDA has [approved multiple generics for ambrisentan tablets](#). With the approval of these first generics and their associated risk evaluation and mitigation strategy (REMS) programs, patients will now have access to additional products (brand-name and generic) and additional types of pharmacies (retail or specialty) to fill their prescriptions, according to FDA.

The agency also approved two shared-system REMS programs for ambrisentan. The first, the Ambrisentan REMS (formerly the Letairis REMS), comprises the reference listed drug or brand sponsor (Letairis), as well as three abbreviated new drug applications (ANDAs, or generics).

The second program, the PS-Ambrisentan REMS, currently consists of one ANDA sponsor. The PS signifies ?parallel system? to assist in differentiating the programs within the market.

For more information, including action items prescribers, patients, and pharmacists should complete to access these additional options, see the First Generic Drug Approvals [section](#) of FDA's website.

Medication Monitor Categories:

[Supplemental Approvals](#)

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