

Dear Colleague:

The California Department of Public Health has been notified that as of July 13, 2020 Sanofi has discontinued supplying the following rifampin or rifampin-containing combination products in the U.S.:

- Rifadin[®] (rifampin capsules USP)
 - o 300 mg, bottle of 60
 - o 150 mg, bottle of 30
- Rifamate[®] (rifampin and isoniazid capsules USP), bottle of 60
- Rifater[®] (rifampin, isoniazid and pyrazinamide) tablets, bottle of 60

There are currently no replacements for these combination products on the U.S. market, however there are several other manufacturers of rifampin to replace Rifadin[®]. Rifampin manufacturers commercially operating in the U.S. are shown below (note: list may not be exhaustive). The domestic pharmaceutical market is dynamic, and we will continue to monitor for new combination approvals. In the meantime, this is an unfortunate loss of these unique formulations for TB treatment in California. TB control programs using any of these products should review their current supplies and make alternative arrangements to ensure adequate individual drug supplies.

Please note that these discontinuations are not known to relate to the finding of nitrosamine contaminants in the rifapentine production chain at Sanofi. Sanofi is working with the FDA to review the details of the investigation. Again, we will provide updates to the supply of rifapentine in the U.S. as they become known. In the meantime, short-course options for latent TB treatment include 4 months of daily rifampin (4R) or 3 months of daily isoniazid and rifampin (3HR): <https://www.cdc.gov/tb/topic/treatment/ltbi.htm>

Please don't hesitate to contact Dr. Scott Nabity (Scott.Nabity@cdph.ca.gov) with questions related to this advisory.

Commercially Available Oral Formulations of Rifampin in the United States

Sources: FDA Orange Book & company websites

Oxford Pharmaceuticals LLC.	300 mg capsule	205-434-9649
Sandoz Inc	150mg, 300 mg capsule	800-525-8747
Akorn Inc	150mg, 300 mg capsule	800-932-5676
Lannett Co Inc.	150mg, 300 mg capsule	215-333-9000
Lupin Pharmaceuticals Inc.	150mg, 300 mg capsule	866-587-4617
Major Pharmaceuticals.	300 mg capsule	800-616-2471