



Suboxone[®] (buprenorphine/naloxone) – First-time generic

- On June 14, 2018, the [FDA announced](#) the approval of [Dr. Reddy's Laboratories AB-rated](#) generic version of Indivior's [Suboxone \(buprenorphine/naloxone\)](#) sublingual film.
 - Dr. Reddy's product launched on June 15, 2018.
 - [Indivior announced](#) it will pursue an immediate injunction against Dr. Reddy's "at-risk" launch.
 - In addition, Mylan received FDA approval of an [AB-rated](#) generic version of Suboxone sublingual film on June 14, 2018. Launch plans for this product are pending.
 - Suboxone is a schedule 3 controlled substance.
- Suboxone sublingual film is indicated for treatment of opioid dependence. Suboxone sublingual film should be used as part of a complete treatment plan that includes counseling and psychosocial support.
- Buprenorphine/naloxone is also available generically as a [sublingual tablet](#), a brand sublingual tablet ([Zubsolv[®]](#)) and a brand buccal film ([Bunavail[®]](#)).
 - These formulations carry the same indication as Suboxone sublingual film.
- According to IMS Health, Suboxone had U.S. sales of approximately \$1.86 billion for the most recent twelve months ending in April 2018.



OptumRx[®] specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum[®] company — a leading provider of integrated health services. Learn more at [optum.com](#).

All Optum[®] trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews[®] is published by the OptumRx Clinical Services Department.

©2018 Optum, Inc. All rights reserved.