



Granix[®] (tbo-filgrastim) – Expanded indication and new warnings

- On July 31, 2018, the FDA announced the approval of Teva's **Granix (tbo-filgrastim)**, for the treatment of adult and pediatric patients 1 month and older for reduction in the duration of severe neutropenia in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.
 - Previously, Granix was only approved to treat adult patients for this same indication.
- The safety and efficacy of Granix have been established for pediatric patients 1 month to < 17 years old.
 - Use of Granix in these age groups is supported by evidence from adequate and well-controlled studies of Granix in adults.
 - Additional safety and pharmacokinetics data is available from a study of 50 pediatric patients with solid tumors treated with Granix for chemotherapy-induced neutropenia. The pharmacokinetics and safety profile of Granix in the pediatric population were similar to those seen in adults.
- In addition, updates were made the *Warnings and Precautions* section of the Granix drug label regarding leukocytosis, simultaneous use with chemotherapy and radiation therapy not recommended, nuclear imaging, and aortitis.
 - Consult the Granix drug label for additional information about these updates.
- The recommended dosage of Granix for all patients is 5 mcg/kg per day administered as a subcutaneous injection.
 - Granix may be administered by a healthcare professional, a patient or caregiver.
 - Administer the first dose of Granix no earlier than 24 hours following myelosuppressive chemotherapy.
 - Do not administer Granix within 24 hours prior to chemotherapy.
 - Daily dosing with Granix should continue until the expected neutrophil nadir is passed and the neutrophil count has recovered to the normal range.
 - Monitor complete blood count prior to chemotherapy and twice per week until recovery.



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.