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.