Adempas® (riociguat) – New Contraindication

- On January 17, 2017, the FDA approved new information to the *Contraindications* section of the Adempas (riociguat) drug label pertaining to pulmonary hypertension associated with idiopathic interstitial pneumonias.

- Adempas is indicated for the treatment of adults with persistent/ recurrent chronic thromboembolic pulmonary hypertension (CTEPH), (WHO Group 4) after surgical treatment, or inoperable CTEPH, to improve exercise capacity and WHO functional class and for the treatment of pulmonary arterial hypertension, (WHO Group 1), to improve exercise capacity, WHO functional class and to delay clinical worsening.

- In addition, the *Contraindications* and *Drug Interactions* sections pertaining to use with PDE inhibitors were updated with new information: do not administer within 24 hours of sildenafil (Revatio®, Viagra®). Do not administer 24 hours before or within 48 hours after tadalafil (Adcirca®, Cialis®).

- The *Dosage and Administration* part of the drug label was updated with the section, Transitioning to and from Adempas:

    — Discontinue sildenafil at least 24 hours prior to administering Adempas.
    — Discontinue tadalafil at least 48 hours prior to administering Adempas.
    — Discontinue Adempas at least 24 hours prior to administering a PDE5-inhibitor.

- Similar updates were made to the Medication Guide.

- Adempas carries a boxed warning for embryo-fetal toxicity.