Siklos® (hydroxyurea) – Expanded indication

- On December 7, 2021, the FDA approved Medunik's Siklos (hydroxyurea), to reduce the frequency of painful crises and to reduce the need for blood transfusions in adult and pediatric patients, 2 years of age and older, with sickle cell anemia with recurrent moderate to severe painful crises.
    - Siklos was previously approved for this indication in pediatric patients only.
- The approval of Siklos for the expanded indication was based on ESCORT-HU 1077, in 370 evaluable adult patients who were naïve to hydroxyurea treatment. The incidence and number of vaso-occlusive events, hospitalizations, acute chest syndrome and blood transfusions in the 12-month period before treatment and after initiation of treatment decreased after 12 months of Siklos treatment.
- Siklos carries a boxed warning for myelosuppression and malignancies.
- The most common adverse reactions (> 10%) with Siklos use in adults were infections, headache and dry skin.
- The recommended initial dose of Siklos for treatment of adults with sickle cell anemia is 15 mg/kg once daily based on patient's actual or ideal weight, whichever is less. The dosage can be adjusted based on blood counts and hematologic recovery.
- Refer to the Siklos drug label for complete dosing recommendations in adults and dosing in pediatric patients.