Zytiga® (abiraterone acetate) – Safety updates

- On June 3, 2019, the FDA approved updates to the *Warnings and Precautions* section of the Zytiga (abiraterone acetate) drug label.

- Zytiga is approved for use in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer and metastatic high-risk castration-sensitive prostate cancer.

- The *Warning and Precaution* subsection regarding hypokalemia, fluid retention, and cardiovascular adverse reactions due to mineralocorticoid excess was updated with information regarding risk of QT prolongation and Torsades de Pointes.

    — In postmarketing experience, QT prolongation and Torsades de Pointes have been observed in patients who develop hypokalemia while taking Zytiga.
    — Patients whose underlying medical conditions might be compromised by increases in blood pressure, hypokalemia, or fluid retention should be closely monitored.

- The *Warnings and Precautions* section was also updated to include information regarding increased fractures and mortality in combination with radium Ra 223 dichloride and embryo-fetal toxicity.

    — Zytiga plus prednisone/prednisolone is not recommended for use in combination with radium 223 dichloride outside of clinical trials.
    — The safety and efficacy of Zytiga have not been established in females. Animal studies have shown that Zytiga can cause fetal harm and loss of pregnancy.

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