

Safety Alert

June. 2026

pegylated liposomal doxorubicin – Renal-limited thrombotic microangiopathy

EDA performs label update to include the following:

Undesirable effects

Renal and urinary disorders

Renal-limited thrombotic microangiopathy: frequency – not known

Background:

Thrombotic microangiopathy (TMA) is a condition characterized by the formation of blood clots in small blood vessels, which can lead to organ damage.

Renal-limited thrombotic microangiopathy refers specifically to TMA confined to the kidneys, where small blood vessels within the kidney become blocked, impairing kidney function.

Key Characteristics:

- Decreased urine output or changes in urine color
- Elevated creatinine and blood urea nitrogen (BUN) indicating impaired kidney function
- Microangiopathic hemolytic anemia: fragmentation of red blood cells due to mechanical damage in occluded small vessels
- Thrombocytopenia: reduced platelet count as platelets are consumed in clot formation
- Hypertension secondary to renal involvement

Biomarkers:

Elevated serum creatinine, reduced platelet count, presence of schistocytes on blood film, and elevated LDH serve as laboratory indicators of TMA-related renal injury.

Therapeutic Indications :

pegylated liposomal is indicated :

- As monotherapy for patients with metastatic breast cancer, where there is an increased cardiac risk.
- For treatment of advanced ovarian cancer in women who have failed a first-line platinum-based chemotherapy regimen.
- In combination with bortezomib for the treatment of progressive multiple myeloma in patients who have received at least one prior therapy and who have already undergone or are unsuitable for bone marrow transplant.
- For treatment of AIDS-related Kaposi's sarcoma (KS) in patients with low CD4 counts (< 200 CD4 lymphocytes/mm³) and extensive mucocutaneous or visceral disease.

Reference

EMA ([click Here](#))

