

SFDA

Safety Communication

[09/NOV/2020]

Potential Risk of Tumor Lysis Syndrome Associated with the Use Pazopanib

The Saudi Food & Drug Authority (SFDA) would like to notify health care professionals about occurrence of tumor lysis syndrome (TLS), including fatal cases, with the use of pazopanib. The risk of developing TLC with use of Pazopanib increases in patients with rapidly growing tumors, high tumor burden, renal dysfunction or dehydration.

The SFDA approved pazopanib for treatment of advanced renal cell carcinoma and advanced Soft-tissue sarcoma. TLS is caused by massive tumor cell lysis with the release of their contents of potassium, phosphate and uric acid into the systemic circulation; leading to hyperuricemia, hyperkalemia, hyperphosphatemia, and hypocalcemia. In serious cases, TLS may cause acute renal failure, cardiac arrhythmias, seizures, or even death.

We reviewed published literature and post marketing databases on the potential risk of TLS with pazopanib use. Our review found three published cases suggesting a causal association between the TLS and pazopanib use. In

addition, we identified 16 spontaneous case reports of TLS reported with the use of pazopanib in the World Health Organization (WHO) database. Out of the 16 cases, five cases reported fatal outcomes. TLS occurred 1-22 days after initiating therapy of pazopanib. Based on the WHO causality assessment system, one case showed a probable association and five cases showed possible association between TLS and pazopanib. The rest of cases were evaluated as un-assessable due to insufficient information.

The SFDA advises health care professional that patients at increased risk of TLS should be closely monitored and treated as clinically indicated. Preventative measures, such as treatment of high uric acid levels and intravenous hydration, should be considered prior to initiation of pazopanib treatment.

Call for reporting:

The SFDA urges both healthcare professionals and patients to report ADRs related to use of any medication to the SFDA using the following contact information:

The National Pharmacovigilance Centre (NPC):

Fax: +966-11-205-7662

SFDA Call Center: 19999

E-mail: npc.drug@sfda.gov.sa

Website: <https://ade.sfda.gov.sa>