

Safety Alert

May 2025

Oxaliplatin- risks of Splenomegaly & Microangiopathic haemolytic anaemia associated with haemolytic uraemic syndrome

EDA performs label update to include the following:

Special warnings and precautions for use

Liver disorders

In case of abnormal liver function test results, **splenomegaly** or portal hypertension which does not obviously result from liver metastases, very rare cases of drug-induced hepatic vascular disorders should be considered.

Undesirable Effects:

Microangiopathic haemolytic anaemia associated with haemolytic uraemic syndrome (HUS) or Coombs positive haemolytic anaemia

Background:

splenomegaly

Splenomegaly is defined as enlargement of the spleen, measured by size or weight.

Hemolytic-uremic syndrome (HUS)

is a clinical syndrome characterized by progressive kidney failure that is associated with microangiopathic hemolytic anemia and thrombocytopenia. HUS is the most common cause of acute kidney injury in children and is increasingly recognized in adults.

Therapeutic Indication:

Oxaliplatin in combination with 5-fluorouracil (5-FU) and folinic acid (FA) is indicated for:

- adjuvant treatment of stage III (Dukes' C) colon cancer after complete resection of primary tumour
- treatment of metastatic colorectal cancer

References:

EMA ([Click here](#))