

Safety Alert

Jun 2024

Sunitinib – Risk of Hyperammonaemic encephalopathy

EDA performs label update to include the following:

Special warnings and precautions for use

Hyperammonaemic encephalopathy

Hyperammonaemic encephalopathy has been observed with sunitinib. In patients who develop unexplained lethargy or changes in mental status, ammonia level should be measured and appropriate clinical management should be initiated.

Undesirable effects

Nervous system disorders

Not Known: *Hyperammonaemic encephalopathy*

Background:

Therapeutic Indication

Gastrointestinal stromal tumour (GIST)

Sunitinib is indicated for the treatment of unresectable and/or metastatic malignant gastrointestinal stromal tumour (GIST) in adults after failure of imatinib treatment due to resistance or intolerance.

Metastatic renal cell carcinoma (MRCC)

Sunitinib is indicated for the treatment of advanced/metastatic renal cell carcinoma (MRCC) in adults.

Pancreatic neuroendocrine tumours (PNET)

Sunitinib is indicated for the treatment of unresectable or metastatic, well-differentiated pancreatic neuroendocrine tumours (PNET) with disease progression in adults.

References:

EMA ([Click here](#))