

Safety Alert

Aug 2025

Meropenem –Risk of Drug-induced liver injury (DILI)

EDA performs label update to include the following:

Special warnings and precautions for use

Drug-induced liver injury (DILI)

Hepatic function should be closely monitored during treatment with meropenem due to the risk of DILI. If severe DILI occurs, treatment discontinuation should be considered as clinically appropriate. Meropenem should be reintroduced only if assessed as essential for treatment.

Use in patients with liver disease: patients with pre-existing liver disorders should have liver function monitored during treatment with meropenem. There is no dose adjustment necessary

Background:

Therapeutic Indication

Meropenem is indicated for the treatment of the following infections in adults and children aged 3 months and older.

- Severe pneumonia, including hospital and ventilator-associated pneumonia
- Broncho-pulmonary infections in cystic fibrosis
- Complicated urinary tract infections
- Complicated intra-abdominal infections
- Intra- and post-partum infections
- Complicated skin and soft tissue infections
- Acute bacterial meningitis

Drug-induced liver injury (DILI)

Drug-induced liver injury (DILI) is an acute or chronic liver injury secondary to drugs or herbal compounds it is common and nearly all classes of medications can cause liver disease. Most cases of DILI are benign, and improve after drug withdrawal. It is important to recognize and remove the offending agent as quickly as possible to prevent the progression to chronic liver disease and/or acute liver failure.

References:

MHRA ([Click Here](#))