

Gambro MARS® receives FDA 510(k) clearance for treatment of Hepatic Encephalopathy



Gambro announced on January 24, that the U.S. Food and Drug Administration (FDA) expanded the cleared indications for its Molecular Adsorbent Recirculating System® (MARS) to include the treatment of hepatic encephalopathy (HE) due to a decompensation of a chronic liver disease.

Hepatic Encephalopathy (HE) is a complex neuropsychiatric syndrome that affects many chronic liver failure patients. It is caused by an accumulation of circulating toxins normally removed by the liver. HE presents with a broad spectrum of clinical manifestations, ranging from mild confusion to severe coma. This syndrome is associated with significant morbidity and mortality.

"This marks a significant step in supporting patients with chronic liver failure who become acutely ill," said Dr. Tarek Hassanein, Medical Director, Southern California Liver Centers. "This therapy may help patients suffering from critical health conditions associated with HE."

MARS removes both protein-bound and water-soluble toxins from the blood using a recirculating albumin solution regenerated by the patented MARS charcoal and resin absorbers. This allows for continued use of the albumin in the circuit for six to eight hours of therapy.

"The expanded indication for MARS offers hepatologists a new therapy to treat chronic liver patients," said Stuart Paul, President of Gambro Americas. "Gambro is pleased to offer another innovation in extracorporeal therapies. It's a reflection of our dedication to creating breakthrough solutions to improve health and advance science."

MARS has been in clinical use outside the U.S. since 1993 and commercially available since 1999. In the U.S., in addition to treating HE, MARS is cleared for use in the treatment of drug overdose and poisonings. In other markets, its clinical indications are many, including acute on-chronic liver failure, acute liver failure, graft dysfunction after liver transplantation, liver failure after hepatic resection, intractable pruritus in cholestatic liver diseases, and drug overdose and poisoning.

MARS is the most widely used extracorporeal liver support therapy. It is used in 45 countries around the world, and its safety and efficacy have been demonstrated by clinical experience with more than 15,000 patients (about 45,000 treatments) who have benefited from its use.

Source: Gambro

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