

Malta, 20 March 2006
Circular No. P05/2006

Dear Medical Practitioners,

RE: Albumin Therapy in Critically-ill Patients

Following the publication of the SAFE study (1), the Medicines Authority draws your attention to safety concerns with respect to the administration of albumin in critically-ill patients. The status of the authorised use of albumin in Malta, is for restoration and maintenance of circulating blood volume where volume deficiency has been demonstrated and use of a colloid, such as albumin is appropriate.

The Medicines Authority recommends prescribers that:

Albumin should be used with caution in conditions where hypervolaemia and its consequences or haemodilution could represent a special risk for the patient. Examples of such conditions are:

- decompensated cardiac insufficiency
- hypertension
- oesophageal varices
- pulmonary oedema
- haemorrhagic diathesis
- severe anaemia
- renal and post-renal anuria

If comparatively large volumes are to be replaced, controls of coagulation and haematocrit are recommended. Care must be taken to ensure adequate substitution of other blood constituents (coagulation factors, electrolytes, platelets and erythrocytes). If haematocrit falls below 30% packed red cells should be given to maintain the oxygen transport capacity of blood.

Note that hypervolaemia may occur if the dosage and rate of infusion are too high. While, at the first clinical signs of cardiovascular overload (headache, dyspnoea, jugular vein congestion), or increased blood pressure, raised venous pressure and pulmonary oedema, the infusion should be stopped. Additionally, diuresis or cardiac output are recommended to be increased according to the severity of the clinical situation.

Reference:

1. The SAFE study investigators. A comparison of Albumin and Saline for Fluid Resuscitation in the Intensive Care Unit. *N Engl J Med.* 2004 May 27;350(22):2247-56.