

**ANNEX**

**CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE  
USE OF THE MEDICINAL PRODUCT TO BE IMPLEMENTED BY THE MEMBER  
STATES**

**CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF MEDICINAL PRODUCT TO BE IMPLEMENTED BY THE MEMBER STATES**

The Member States should ensure that all conditions or restrictions with regard to the safe and effective use of the medicinal product described below are implemented:

The National Competent Authorities shall agree the details of an education programme for patients and health care professionals with the MAH, who must implement such programme nationally to ensure provision of educational material to patients and health professionals containing information:

- on the risk factors for and prevention of peritonitis in PD (peritoneal dialysis) patients.
- on the risk factors for and prevention of arterio-venous fistula site complications in HD (haemodialysis) patients
- on the increased risk of vitamin deficiency in chronic kidney disease patients and the need for vitamin supplementation