Risk Evaluation and Mitigation Strategy (REMS)

Shared System for Alosetron

Selective 5-HT₃ antagonist

I. GOAL(S):

The goals and objectives of the Alosetron REMS Program are to mitigate the risks of ischemic colitis (IC) and serious complications of constipation (CoC) associated with alosetron hydrochloride (hereinafter, referred to as alosetron) by:

- Informing prescribers of alosetron about:
  - the serious risks of IC and serious CoC associated with alosetron
  - the importance of understanding that alosetron should only be used in severely affected diarrhea-predominant irritable bowel syndrome patients for whom the benefits exceed the risks.
  - the importance of counseling patients about the risks of IC and serious CoC

- Informing patients about the risks of IC and CoC and actions to take should they experience early warning signs and symptoms of these risks.

II. REMS ELEMENTS:

A. Elements to Assure Safe Use