FDA Required SYMLIN REMS Safety Information

SYMLIN REMS Purpose

The purpose of the SYMLIN REMS program is to inform health care providers about the following serious risks of SYMLIN:

- Increased risk of severe hypoglycemia, particularly in patients with type 1 diabetes.
- Importance of insulin dose reduction

Counsel and instruct your patients on insulin dose reduction to minimize the risk of hypoglycemia.

- Proper patient selection: SYMLIN is contraindicated in patients with any of the following:
  - Hypoglycemia unawareness
  - Confirmed gastroparesis
  - Severe hypersensitivity to SYMLIN or any of its product components

Please see the non-promotional SYMLIN Factsheet, reviewed by the FDA for more detailed safety information.

Risk Evaluation and Mitigation Strategy (REMS)

A REMS is a strategy to manage known or potential serious risks associated with a drug product and is required by the Food and Drug Administration (FDA) to ensure that the benefits of a drug outweigh its risks.

The FDA has issued a REMS for SYMLIN.

BROWSER PAGE TITLE:
SYMLIN REMS page

PROGRAMMING NOTES:
1) AstraZeneca will include a prominent link on the SYMLIN HCP homepage for REMS materials. The link will direct HCPs to this separate webpage (http://www.SYMLINREMS.com).

2) This REMS website is independent of link to the promotional and/or commercial website and non-REMS materials about the product.

3) The REMS website will be accessible directly through a search engine.