

Subject: Domperidone
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Preface:

If you are considering obtaining Domperidone by this method, you should check the US FDA website for the most current regulation.

How To Obtain Domperidone

On June 7, 2004, the Food and Drug Administration (FDA) warned compounding pharmacies and firms that supply domperidone for use in compounding that it is illegal to compound domperidone and issued an import alert advising FDA field personnel that they may detain shipments of finished drug products and bulk ingredients containing domperidone. These actions were the result of the Agency's concern about the potential public health risks associated with the use of domperidone by lactating women. Although FDA has determined that domperidone should not be compounded or used to enhance breast milk production in lactating women, there are some patients with severe gastrointestinal disorders, such as severe gastroparesis or severe GI motility disorders that are refractory to standard therapy, who may benefit from the drug and in whom the drug's benefits outweigh its risks.

FDA encourages physicians who would like to prescribe domperidone for their patients with severe gastrointestinal disorders that are refractory to standard therapy to open an Investigational New Drug Application (IND). An IND is a request for FDA authorization to administer an investigational drug to humans. Such authorization would allow the importation, interstate shipment, and administration of the drug even though it is not approved for sale in the U.S.

For questions relating to domperidone INDs contact the Division of Drug Information, toll free at (888) INFO-FDA or (301) 796-3400.

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