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FDA Talk Paper: FDA Warns Against Women Using Unapproved Drug, Domperidone, to Increase Milk Production

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In response to reports that women may be using an unapproved drug, domperidone, to increase milk production (lactation), the Food and Drug Administration (FDA) is warning breastfeeding women not to use this product because of safety concerns. Today, FDA also issued six letters to pharmacies that compound products containing domperidone and firms that supply domperidone for use in compounding.

The Agency also is issuing an Import Alert which alerts FDA field personnel to be on the lookout for attempts to import this drug so that it can be detained and refused admission into the U.S. if appropriate.

FDA took these actions because it has become aware that some women who breastfeed and/or pump breast milk are purchasing this drug, domperidone, from compounding pharmacies and from sources in foreign countries to increase breast milk production. Domperidone may increase the secretion of prolactin, a hormone that is needed for lactation.

Although domperidone is approved in several countries outside the U.S. to treat certain gastric disorders, it is not approved in any country, including the U.S., for enhancing breast milk production in lactating women and is also not approved in the U.S. for any indication.

The agency is concerned with the potential public health risks associated with domperidone. There have been several published reports and case studies of cardiac arrhythmias, cardiac arrest, and sudden death in patients receiving an intravenous form of domperidone that has been withdrawn from marketing in a number of countries. In several countries where the oral form of domperidone continues to be marketed, labels for the product contain specific warnings against use of domperidone by breastfeeding women and note that the drug is excreted in breast milk that could expose a breastfeeding infant to unknown risks. Because of

the possibility of serious adverse effects, FDA recommends that breastfeeding women not use domperidone to increase milk production.

The FDA recognizes the immense health benefits that breast milk provides for a nursing infant and is taking these actions today not to discourage women from breastfeeding but rather to warn them not to use this particular drug while they are breastfeeding.

The letters issued by FDA today stated that all drug products containing domperidone (whether compounded or not) violate the Federal Food, Drug, and Cosmetic Act (the Act) because they are unapproved new drugs and misbranded. In addition, distribution within the U.S., or importation of domperidone-containing products, violates the law. FDA informed the warning letter recipients that further violations of the Act may result in enforcement actions including seizure and injunction.

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US FDA page link as of 13 August 2013:

<http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm173886.htm>