QUALITY ASSURANCE REVIEW FOR DOMPERIDONE

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Domperidone (trade names Motilium, Motillium, Motinorm Costi, Nomit and Molax) is a peripheral, specific blocker of dopamine receptors.

The uses or indications of domperidone vary between nations. For instance, in Italy it is used in the treatment of gastroesophageal reflux disease and in Canada, the drug is indicated in upper gastrointestinal motility disorders and to prevent gastrointestinal symptoms associated with the use of dopamine agonist antiparkinsonian agents. In some nations, including Australia domperidone is as a therapy for mothers who are having difficulty breastfeeding with uncertain result. In the United States, domperidone is not approved for this or any other use. 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.

Moreover, according to the publication's hypothesis, the number of sudden deaths connected to domperidone could have been between 25 and 120 in 2012 in France. In 2011, the risk of sudden death was flagged up by the French Medicines Agency (Agence Nationale de Sécurité du Médicament et des Produits de Santé, ANSM) and the primary firm who market the product in France. The ANSM also warned against the unauthorised use of Motilium to ease breastfeeding. According to the periodical, which used medical insurance data, approximately seven per cent of adults, which translates to about three million people, received a prescription for the medicine in France in 2012. It is estimated that 23 million people in France received at least one prescription for domperidone between 2003 and 2013. In March 2013, a review of all domperidone-containing medicines was launched by the EMA at the request of Belgium. The Belgian Medicines Agency raised concerns over the safety of the medicine for patients with heart problems. Domperidone-containing medicines could be purchased over-the-counter in Belgium until the end of 2013, when a new law came into action, making it available only with a prescription. The EMA has started a full review on the effects of domperidone, evaluating its benefit-to-risk ratio. The conclusion to the review is expected to be published in March of this year.